



Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Closed Meeting Agenda

Wednesday, April 26, 2023-5:00 pm

Kathleen King Community Room - 85 Nielson Street, Watsonville

<https://zoom.us/j/93443061917>

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

Agenda documents are available for review in person at Watsonville Community Hospital, 75 Nielson Street, Hospital Main Lobby-Visitors Desk; and electronically on the Pajaro Valley Healthcare District's website, at: PVHCDHC.ORG. To view online, visit the Board's website at: [PVHCDHC.ORG](https://www.pvhcdhc.org) and select the meeting date to view the agenda and supporting documents. Written comments on agenda items may also be submitted to the Board by email or US Mail. Comments received after 4 p.m. on the day of the meeting and before the end of the meeting will be included in the official record.

Email: info@pvhcd.org

- Emailed documents may take up to 24 hours to be posted
- Please include the agenda item number

U.S. Mail:

PVHCD Board of Directors
75 Nielson Street
Watsonville, CA 95076

For additional information, call 831.763.6040 or email info@pvhcd.org

ACCOMMODATIONS FOR PERSONS WITH DISABILITIES

The Pajaro Valley Health Care District Hospital Corporation does not discriminate on the basis of disability, and no person shall, by reason of a disability, be denied the benefits of its services, programs, or activities. If you are a person with a disability and wish to participate in the meeting and require special assistance in order to participate, please call (831)763-6040 or email info@pvhcd.org at least three business days in advance of the meeting to make arrangements. Persons with disabilities may request a copy of the agenda in an alternative format.

TRANSLATION SERVICES/SERVICIOS DE TRADUCCIÓN

Spanish language translation is available on an as needed basis. Please make advance arrangements at least three business days before the meeting at by calling at (831) 763.6040 or by emailing at info@pvhcd.org.

Las sesiones de la Mesa Directiva pueden ser traducidas del inglés al español y del español al inglés. Por favor llame por lo menos tres días hábiles antes de la junta al (831) 763.6040 o envíe un correo electrónico a info@pvhcd.org para solicitar interpretación.

**Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Agenda-Wednesday, April 26, 2023**

Call to Order

Roll Call

Public Comment on Matters Not on the Agenda

Time is set aside for members of the public to address the Board on any item not on the Board Agenda (not to exceed two minutes), which is within the subject matter jurisdiction of the Board.

Comments regarding items included on the Agenda will be heard before the item is discussed by the Board.

No action or discussion shall be taken on any item presented except that any Board Member may respond to statements made or questions asked or may ask questions for clarification. All matters of an administrative nature will be referred to staff. All matters relating to the Board will be noted in the minutes and may be scheduled for discussion at a future meeting or referred to staff for clarification and a report.

Public Comment on Matters on the Agenda

Adjourn to Closed Session

- 1. Conference with Labor Negotiators** (Government Code 54957.6)
Agency Negotiator: Allyson Hauck; California Nurses Association (CAN)
Contact: Allyson Hauck, Chief Human Resources Officer
- 2. Public Employee Recruitment Update** (Government Code 54957(b)(1))
Conference with Labor Negotiators (Gov't Code 54957.6)
Title Chief Executive Officer
Contact: Allyson Hauck, Chief Human Resources Officer
- 3. Hearings/Reports** (Health and Safety Code HSC § 1461 and 32155)
Reports of Patient Safety and Quality Committee, Medical Staff Credentials Committee,
Medical Staff Interdisciplinary Practice Committee and Quality Dashboard.
Contact: Executive Sponsor-Dr. Angel, Chief of Staff

Adjournment

This agenda was posted in accordance with the California Brown Act. Any materials related to an item on this Agenda submitted to the Board after distribution of the agenda packet will be made available to the public in accordance with Government Section 54957.5.



Board Members

- John Friel (Chair)
- Dr. Katherine (Katie) Gabriel-Cox
- Dr. Joe Gallagher
- Jose A. (Tony) Nuñez
- Marcus Pimentel

Regular Meeting Agenda

Wednesday, April 26, 2023-5:00 pm

(This meeting will begin after Closed Session)

Zoom: <https://zoom.us/j/93443061917>

Phone: +1 669 900 9128 WEBINAR ID: 934 4306 1917

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**Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Agenda- Wednesday, April 26, 2023**

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

Public Comment on Matters Not on the Agenda

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Comments from Board Members

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion. Members of the public must request that a Board Member pull an item from the Consent Agenda for discussion prior to the start of the meeting.

1. Minute Approval: March 2023

Recommendation: Pass a **Motion** approving the minutes of the March 22, 2023 and March 29, 2023.

Contact: Dawn Bullwinkel, Consultant Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. Policies/Policy Summary Approval: April 2023

Recommendation: Pass a **Motion** approving the Policies/Policy Summary.

Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

3. Conflict of Interest Code

Recommendation: 1) Pass a **Resolution** approving the Conflict of Interest Code pursuant to the Political Reform Act of 1974; and 2) direct the board clerk to forward the Conflict of Interest Code to the Fair Political Practice Commission for acceptance.

Contact: Matko Vranjes, Interim Chief Executive Officer

Matko_Vranjes@Watsonvillehospital.com

4. Limited Authority Retirement Plan Amendments

Recommendation: Pass a **Resolution** authorizing delegating limited “settlor: authority to the Chief Human Resources Officer (CHRO) to make certain types of plan amendments.

Contact: Allyson Hauck, Chief Human Resources Officer

Discussion

5. Chief Executive Officer Matko Vranjes Oral Report on Operational Hospital Activities

Recommendation: Receive and file.

Contact: Matko Vranjes, Chief Executive Officer

6. Chief Financial Officer Monthly Financial Performance

Recommendation: Receive and file.

Contact: Julie Peterson, Chief Financial Officer

7. Medical Executive Committees Reports Report March 2023

Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of April 2023; and 2) the Medical Executive Committee (MEC) recommendation appointing Surgery Department Vice Chair – Sarah Brant, MD.

Contact: A Janelle Rasi, M.D., Vice Chief of Staff Chair, Medical Executive Committee

Adjournment

This agenda was posted in accordance with the California Brown Act. Any materials related to an item on this Agenda submitted to the Board after distribution of the agenda packet will be made available to the public in accordance with Government Section 54957.5.



Board Report

Meeting Date: April 26, 2023

Report Type: Consent

Title: Minutes Approval: March 2023

Recommendation: Pass a Motion approving the minutes for March 22, 2023 and March 29, 2023.

Contact: Dawn Bullwinkel, Consultant Board Clerk

Analysis

After each Board meeting, the Board Clerk composes the DRAFT minutes noting the action taken by the board. Those DRAFT minutes are presented to the Board Members for their approval as a permanent record of the meeting actions.

Financial Impact: None

Attachments:

- A. March 22, 2023 Closed
- B. March 22, 2023 Regular
- C. March 29, 2023 Closed
- D. March 29, 2023 Regular

**Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Minutes - Wednesday, March 22, 2023**

Call to Order at 10:30 am.

Roll Call

Present-Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on Agenda-None.

Adjourn to Closed Session

1. **Public Employee Appointment (Gov't Code 54957(b)(1))**
Title: Interim Chief Executive Officer
2. **Conference with Labor Negotiators (Gov't Code 54957.6)**
Agency Designated Representative: Chief Human Resources Officer
Unrepresented Employee: Interim Chief Executive Officer

Reconvene Opens Session/Report out on Closed Session, if any

3. **Consideration of Appointment of Interim Chief Executive Officer (CEO)**
Contact: Chief Human Resources Officer

Moved/Seconded: Nunez/Cox

Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Action: Passed **Motion No. 020-2023** 1) appointing Matko Vranjes as Interim Chief Executive Officer upon current CEO's departure expected to be April 11, 2023; and 2) creating a Permanent CEO Search Ad Hoc Committee with Director Pimentel and Chair Friel.

Adjourned at 12:53 pm.

**Pajaro Valley Health Care District Hospital Corporation
Special Meeting Minutes- Wednesday, March 22, 2023**

Call to Order-9:36 am

Roll Call

Present-Directors Cox, Gallagher, Nunez arrived 10:22 am, Pimentel and Chair Friel

Agenda Modification Consideration-None.

Discussion

1. Strategic Planning-Three to Five Year Goals

Moved/Seconded: Gallagher/Pimentel

Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Action: Pass **Motion No. 021-2023** directing Chartis advisory firm to pause the scheduled focus group meetings and to meet with staff and return on March 29, 2023 with a revised Strategic Planning timeline.

Contact: Steven Salyer, Chief Executive Officer

Adjourned- 11:25 am.

**Pajaro Valley Health Care District Hospital Corporation
Closed Meeting Minutes- Wednesday, March 29, 2023**

Call to Order at 5:06 pm.

Roll Call

Present-Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Public Comment on Matters on Agenda-None

Adjourn to Closed Session at 5:09 pm.

1. Conference with Labor Negotiators (Gov't Code 54957.6)

Agency Negotiator: Allyson Hauck; California Nurses Association (CAN)

Contact: Allyson Hauck, Chief Human Resources Officer

2. Hearings/Reports (Health and Safety Code HSC § 1461 and 32155)

Reports of Patient Safety and Quality Committee, Medical Staff Credentials Committee, Medical Staff Interdisciplinary Practice Committee and Quality Dashboard.

Contact: Executive Sponsor-Dr. Angel, Chief of Staff

**Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Minutes- Wednesday, March 29, 2023**

Call to Order at 6:32 pm.

Roll Call:

Present-Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Closed Session Report- None

Agenda Modification Consideration-None

Public Comment on Matters Not on the Agenda

- a) Dan Whiteside-healthcare consultant volunteered to sit on the CEO executive search panel

Comments from Board Members

- a) Director Pimentel: Gratitude for the support and assistance by everyone during the recent disaster
- b) Chair Friel: Disaster impacts and ensuring the hospital will continue to support employees and constituency
- c) Chair Friel: March 29, 1973-National Vietnam Veterans Day and Gratitude to Vietnam Veterans
- d) Director Nunez: Encouraged donations to Community Foundations of Santa Cruz and/or Monterey County for those that cannot access federal assistance.
- e) Director Nunez: Steven Salyer, Chief Executive Officer-thank you for your gift of service and leadership over the last year
- f) Chair Friel: Steven Salyer, Chief Executive Officer- an "Unsung Hero"

Consent

All items listed under the Consent Calendar are considered and acted upon by one Motion.

Moved/Seconded: Pimentel/Nunez

Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

1. Minute Approval: February 22, 2023

Action: Passed **Motion No. 022-2023** approving the minutes for February 22, 2023.

Contact: Dawn Bullwinkel, Consultant Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. Policies/Policy Summary Approval: March 2023

Action: Passed **Motion No. 023-2023** approving the Policies/Policy Summary.

Contact: Sherri Torres, Chief Nursing Officer, Sherri.StoutTorres@Watsonvillehospital.com

3. Cash Advance

Action: Received and filed information regarding \$1,000,000 cash advance through Central California Alliance for Health.

Contact: Julie Peterson, Chief Financial Officer

Discussion

4. Strategic Planning-Discuss Revised Timeline

Action: Directed 1) the revised Strategic Planning timeline pausing in April except for the survey outreach; 2) the scheduling of special meetings for May 1, 2023, May 15, 2023, June 19, 2023 in addition to the May 31, 2023 regular meeting for Strategic Planning; and 3) the addition of survey outreach enhancements such as requesting location/zip code on survey, posting throughout the hospital/regionally including a QR Code, newspapers, social media and in person hard-copy outreach.

Contact: Steven Salyer, Chief Executive Officer

5. Salary for Interim Chief Executive Officer Matko Vranjes

Moved/Seconded: Nunez/Cox

Yes: Directors Cox, Gallagher, Nunez, Pimentel and Chair Friel

Action: Passed **Motion No. 024-2023** approving an annual salary of \$331,250 for Interim Chief Executive Officer Matko Vranjes beginning April 11, 2023. Current benefits and other terms and conditions of employment will continue during the Interim Appointment.

Contact: Allyson Hauck, Chief Human Resources Officer

6. Chief Financial Officer Monthly Financial Performance

Action: Received and filed.

Contact: Julie Peterson, Chief Financial Officer

7. Medical Executive Committees (MEC) Reports March 2023

Action: Passed **Motion No. 025-2023** approving 1) MEC March 2023 Credentials Report; 2) MEC March 2023 Interdisciplinary Practice Credentials Report; 3) Medical Staff Items and 4) MERP-YTD 2022.

Contact: Clay Angel, M.D., Chief of Staff Chair, Medical Executive Committee

Adjourned at 7:32 pm.



Board Report

Meeting Date: April 26, 2023

Report Type: Consent

Title: Policy/Summaries April 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of March 2023.


Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

Analysis

As required under Title, 22, CMS and The Joint Commission (TJC), a list of regulatory required policies with a summary of changes is provided for your approval.

Financial Impact: None.

Attachment A:
Reports

		Watsonville Community Hospital POLICY APPROVAL SUMMARY REPORT		
Committee: BOT				
Reporting Period: April 2023				
As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.				
Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Nursing (NUR)				
Pressure Injury Prevention Management Wound Risk Assessment	NUR1986	Re-structure to better define sections for "Purpose", "Policy" and "Procedure"	Re-structure to better define sections for "Purpose", "Policy" and "Procedure"	Author: Pharmacy, Respiratory Director, Wound 01/31/23 QCC: 02/2023 MEC: 02/21/2023 BOT:
Facilities (FAC)				
Hot Work Permit	EC.02.06.05.02.g	Updated New Template: fixing some language for clarity (for example, the previous version said "it is the policy of <<facility>>.... And the new version changed to "it is the policy of Watsonville Community Hospital....."	Regularly Scheduled Review	Author: Facility Director 11/2022 FAC: 03/10/2023 EOC: 02/23/2023 VP/Sr.Leaders/CEO: 04/11/2023 MEC: N/A BOT:
Emergency Department (ED)				
Massive Transfusion Protocol	XXXX	New Policy: Replacing #2240, Rapid Autologous Transfusion System	Policy is updated to meet current evidence based guidelines and updated interdisciplinary hospital wide response process'	Author: ED Department/Laboratory Director: 02/2023 CNO: 02/2023 COO:02/23/2023 ED Dept: 04/12/2023 VP/SR.Leader/CEO: 03/2023 MEC: 04/18/2023 BOT:
Laboratory (LAB)				




**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**

Committee: BOT

Reporting Period: April 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Antibody Scree-Gel Ortho Clinical Diagnostic	BB2828	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 11/14/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 02/21/2023 BOT
Cytospin Operating Procedure	HEM2407	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 11/14/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Roche Cobras U411	HEM2507	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 VP/Sr.Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT :
Fecal Occult Blood	HEM2508	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT:

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Committee: BOT				
Reporting Period: April 2023				
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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Urinalysis Microscopic	HEM2582	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/23 MEC: 03/28/2023 BOT:
Critical Value Reporting	HEM131001	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO: VP/Sr. Leader/CEO: 02/15/23 MEC: 03/28/2023 BOT :
Delta Check	HEM131002	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO: VP/Sr. Leader/CEO: 02/15/23 MEC: 03/28/2023 BOT :
E-Signature Result Review	HEM131003	Removed HMN, minor change	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO: VP/Sr. Leader/CEO: 02/15/23 MEC: 03/28/2023 BOT :



Watsonville Community Hospital
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Committee: BOT

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Proficiency Testing	HEM131004	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Quality Control	HEM131005	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Hematology Routine	HEM131006	Revised to reflect new hematology analyzer	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/VP/Sr. Leader/CEO: 02/15//2023 MEC: 03/28/2023 BOT:
Hematology Quality Control	HEM131007	Revised to follow new hematology analyzer.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT:




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Committee: BOT

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Hematek Slide Stainer	HEM131008	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO: VP/Sr. Leader/CEO: 02/15/23 MEC: 03/28/2023 BOT :
Malaria Smears	HEM131010	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT :
Manual Body Fluid Counts	HEM131011	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO:VP/Sr.Leader/CE O: 02/15/2023 MEC: 03/28/2023 BOT :
Pathologist's Review of Hematology Smears	HEM131012	Changed abs lymph from >4.0 to >5.0	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO:VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT:

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Pelger-Huet Anomaly on Manual WBC Differentials	HEM131013	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT :
Polar Bifringence for Crystals	HEM131014	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO:VP/Sr.Leader/CE O: 02/15/2023 MEC: 03/28/2023 BOT :
Sedimentation Rate (Streck- ESR Auto Plus)	HEM131016	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT




**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Stago Compact Coagulation Instrument	HEM131017	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO:02/15/2023 02/15/2023 MEC: 03/28/2023 BOT:
Hematology Downtime	HEM131020	Revised to reflect new hematology analyzer	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Delegation of Laboratory Medical Director Responsibilities	LAB101	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT:

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IQCP General	LAB0002	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Influenza A & B	LAB131031	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Medical Necessity and ABN Form Use	LAB1823	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab.Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



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Clarification of Physician's Orders or Diagnosis Codes	LAB1827	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab.Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Competency Assessment of Testing	LAB1828	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab.Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Confirmation of Verbal Orders	LAB1829	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab.Med. Director: 10/26/2022 COO/CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Correction and Reporting of Laboratory Errors	LAB1830	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab.Med. Director: 10/31/2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Laboratory Instrument Maintenance	LAB1836	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Method Validation Prior to Implementation	LAB1840	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Pending Test Reports	LAB1846	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Specimen Labeling, Receipt, Collection and Transportation	LAB1851	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT




**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**


Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Standing Orders	LAB1853	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Thermometer Verification	LAB1854	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Proficiency Testing Program	LAB1856	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Laboratory Quality Control Policy	LAB1857	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT

		Watsonville Community Hospital POLICY APPROVAL SUMMARY REPORT		
Committee: BOT				
Reporting Period: April 2023				
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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Diseases Reportable	LAB1861	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Lab Technician/Phlebotomist Performance Standards	LAB1866	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Reference Laboratory Approval	LAB1909	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31//2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT

		Watsonville Community Hospital POLICY APPROVAL SUMMARY REPORT		
Committee: BOT				
Reporting Period: April 2023				
As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.				
Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Reference Laboratory Testing	LAB1910	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31//2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Guidelines for Performance of a Venipuncture	LAB2363	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Approved Sites and Conditions for Phlebotomy	LAB2364	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Newborn Screening	LAB2365	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Onsite Outpatient Procedure	LAB2369	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Specimen Collection and Handling	LAB2370	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Lab Specimen Cancellation & Delays	LAB2614	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Specimen Rejection	LAB2730	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Emergency Product Issue to Unknown Patient in Wyngate	LAB2734	New Template. No changes	Regularly Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	LAB2830	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Gastrocult (Gastric Occult Blood and PH Test)	LAB2905	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Fungus	LAB131025	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: 03/28/2023 BOT
Carba NP	LAB131057	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Throat Culture	LAB131058	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 11/14/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
BioFire	MIC 131.068	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT




Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

As required under Title, 22, CMS and The Joint Commission (TJC), please find below a list of regulatory required policies with summary of changes that request your approval.

Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Gram Stain	MIC2144	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 COO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Anaerobic Culture	MIC131002	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Anthrax	MIC131003	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT

		Watsonville Community Hospital POLICY APPROVAL SUMMARY REPORT		
Committee: BOT				
Reporting Period: April 2023				
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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Bacterial Vaginosis Gram Stain	MIC131004	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Body Fluid Culture (excluding CSF, Urine and Blood Cultures)	MIC131011	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Botulism	MIC131012	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Burkholderia	MIC131014	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Catheter Tip	MIC131016	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Beta-Lactamase (Cefinase)Test	MIC131017	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/26/2022 Lab Med. Director: 10/26/2022 VP/Sr.Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT:
Ear Culture	MIC131021	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr.Leader/CEO:02/ 15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
ImmunoCard EHEC	MIC131022	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Eye Culture	MIC131023	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr.Leader/CEO:02/ 15/2023 MEC: 03/28/2023 BOT
Fecal Leukocyte Stain	MIC131024	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Genital Culture	MIC131026	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Germ Tube	MIC131027	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr.Leader/CEO:02/ 15/2023 MEC: 03/28/2023 BOT
Indole	MIC131030	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO/VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
KOH	MIC131032	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO/VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
MIO Media	MIC131040	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
MRSA Latex Agglutination	MIC131041	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
MRSA Screen	MIC131042	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Optochin Disc	MIC131043	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
COVID-19	MIC131069	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT




Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Commercially Prepared Media QC	MIC131108	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Accessioning Cytology Specimen Procedure	PATH2282	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Autopsies	PATH2349	No changes.	Regularly Scheduled Review	Author: Laboratory Director:12/15/2022 CNO/VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Pathology Specimens Policy	PATH2438	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/18/2022 Lab Med. Director: 10/26/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT

		Watsonville Community Hospital POLICY APPROVAL SUMMARY REPORT		
Committee: BOT				
Reporting Period: April 2023				
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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
i-STAT Operations and Testing Procedure	POC2118	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 CNO: VP/Sr. Leader/CEO:02/15/2023 MEC: 03/28/2023 BOT
Point of Care Testing	POC2583	No changes.	Regularly Scheduled Review	Author: Laboratory Director:10/31/2022 Lab Med. Director: 10/31/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: 03/28/2023 BOT
Pharmacy(PHARM)				
Administration of Drugs: Medication Administration Times	PHARM1569	Updated New Template. Meal times changed as a result of CHOW (Change of Ownership) survey, leading to slight discrepancy in medication timing for "before meal".	Regularly Scheduled Review/changed of Ownership	Author: Pharmacy Director 03/2023 PTIC: 03/1/2023 MEC:03/28/2023 BOT:
Parenteral Nutrition Support Monitoring	PHARM 0129	Minor: Changes to Triglyceride monitoring to be consistent with P#1413 below (baseline, then weekly)Weights daily (remove "minimum weekly weights") Update references	Regularly Scheduled Review	Author: FNS, Pharmacy Director, 03/2023 PTIC: 03/1/2023 MEC: 03/28/2023 BOT:



Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Parenteral Nutrition Administration	PHARM1430	Minor: Changes to Triglyceride monitoring to be consistent with P#1413 below (baseline, then weekly)Weights daily (remove “minimum weekly weights”) Update references	Regularly Scheduled Review	Author: Pharmacy Director 03/2023 PTIC: 03/1/2023 MEC: 03/28/2023 BOT:
Fat Emulsion Administration	PHARM1413	Modify (increase) infusion duration to 24 hours to minimize complications resulting from lipid infusions (e.g., fat overload syndrome), Updates/changes to Triglyceride monitoring	Regularly scheduled review	Author: Pharmacy Director 03/2023 PTIC: 03/1/2023 MEC: 03/28/2023 BOT:
Rehabilitation (REHAB)				
Electronic Documentation in Rehab Services	REHAB2784	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :01/23/2023 VP/Sr. Leaders/CEO: 02/15/2023 MEC: 03/28/2023 BOT:
Pain Assessment	REHAB1933	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :01/24/2023 VP/Sr. Leaders/CEO: 02/15/2023 MEC: 03/28/2023 BOT:



**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**

Committee: BOT

Reporting Period: April 2023

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Ultrasound	REHAB1930	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:
Hot Packs	REHAB2066	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:
Electrical Stimulation	REHAB1927	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:
Crutch Training/Fit	REHAB1926	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:
Care of Patients with IV's	REHAB1924	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:



**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Arthroscopy and Arthrotomy	REHAB2062	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/13/2022 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 03/28/2023 BOT:
Iontophoresis Monitoring	REHAB1931	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :02/23/2023 CNO:03/2023 QPSC: 03/2023 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 04/18/2023 BOT:
Patient Discharge	REHAB1928	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :03/22, 03/2023 CNO: 03/2023 QPSC: 03/2023 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 04/18/2023 BOT:
Transporting Patients to and from the Rehab Dept	REHAB1929	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director :12/2022, 01/2023 CNO: 03/2023 QPSC: 03/2023 VP/Sr. Leaders/CEO: 01/17/2023 MEC: 04/18/2023 BOT:



**Watsonville Community Hospital
POLICY APPROVAL SUMMARY REPORT**

Committee: BOT

Reporting Period: April 2023

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Summary Sheet for Outpatient Therapy Services	REHAB1728	No changes.	Regularly Scheduled Review	Author: Rehabilitation Director: 03/06/2023 CNO:03/2023 QPSC: 03/2023 VP/Sr. Leader/CEO: 04/11/2023 MEC: 04/18/2023 BOT:
Enviromental Services				
Cleaning Isolation Patient Room-Discharge/Transfer	EVS8027	Updated New Template. No Changes	Regularly Scheduled Review	Author: EVS/Facility Director :04/07/2023 VP/Sr. Leaders/CEO: 04/11/2023 MEC:N/A BOT:
Cleaning Isolation Patient Room Occupied	EVS8028	Updated New Template. No changes	Regularly Scheduled Review	Author: EVS/Facility Director :04/07/2023 VP/Sr. Leaders/CEO: 04/11/2023 MEC:N/A BOT:
Radiology Dept. (RAD)				
MRI Safety General	RAD2632	Due to the reportable MRI safety incident this policy had a revision made to it. Added information on handheld wand, and changed responsible party to Radiology department from vp ancillary services.	Updated policy to address safety reinforcement following a CDPH reportable safety incident.	Author: Radiology Director: 04/19/2023 FCO: 04/19/2023 Safety Officer: 04/19/2023 VP.Sr.Leader/CEO: 04/19/2023 BOT:



To: Committees: QCC, MEC, BoT

Date: 31 January 2023

From: Jennifer Ura Gavin, Director of Pharmacy, Respiratory Therapy
Liz Nichols, Nurse Manager – Wound & Hyperbaric Treatment Center
Anna Anton, Nurse Manager – Med/Surg, Tele, Critical Care

Re: Policy #NUR1986: Pressure Injury Prevention/Management (Wound Risk Assessment)

Changes:

- Re-structure to better define sections for “Purpose”, “Policy” and “Procedure”
 - I. PURPOSE**
 - A. To provide standardized guidelines to ensure prompt identification of hospital acquired pressure injuries.
 - B. To reduce incidents and severity of hospital acquired pressure injuries.
 - C. To educate staff related to pressure injury prevention.
 - D. To educate patient, family, and others concerning risk of pressure injury development.
 - II. POLICY**
 - A. This policy applies to all hospital departments
 - B. Wounds in this policy do not include post-operative surgical wounds or incisions from an operative site.
 - C. Targeted assessment for the identification of patients at risk to develop wounds and implementing interventions are key to preventing acquired wounds.
 - D. Education of all involved in care of patient is critical in pressure injury prevention.
- Add sections to include Respiratory Therapy skin integrity assessment and documentation:
 - IV. PROCEDURE:
 - A. Skin Risk Assessment
 - 5. Licensed Respiratory Care Practitioner (RCP) shall assess skin integrity when patient is receiving ventilation or oxygen therapy.
 - E. Documentation Requirements
 - 7. RCP will document skin integrity and barrier change and/or cleaning, if applicable.
 - a. If assessment of skin integrity is not possible due to patient condition and/or behavior, reason for inability to provide assessment will be documented.

Policy Title	Pressure Injury Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
Responsible	Nursing Administration	Revised/Reviewed	12/9/2020

I. PURPOSE

- ~~A. Wounds in this policy do not include post-operative surgical wounds or incisions from an operative site.~~
- ~~B. Targeted assessment for the identification of patients at risk to develop wounds and implementing interventions are key to preventing acquired wounds.~~
- ~~AC. To provide standardized guidelines to ensure p~~Prompt identification of ~~a~~all hospital acquired pressure injuries.
- ~~BD. To r~~Reduce ~~in~~ incidents and severity of hospital acquired pressure injuries.
- ~~CE. To e~~Educate staff related to pressure injury prevention.
- ~~DF. To e~~Educate patient, family, and others concerning risk of pressure injury development.

II. POLICY

- A. This policy applies to all hospital departments
- ~~B. Wounds in this policy do not include post-operative surgical wounds or incisions from an operative site.~~
- ~~C. Targeted assessment for the identification of patients at risk to develop wounds and implementing interventions are key to preventing acquired wounds.~~
- ~~D. Education of all involved in care of patient is critical in pressure injury prevention.~~

III. DEFINITIONS

- ✓ A **Hospital Acquired Pressure Injury (HAPI)** is defined as a localized injury to the skin and/or underlying tissue during an inpatient hospital stay.
- ✓ A **Present on Admission (POA) Pressure Injury** is defined as a pressure injury that is **present** at the time the order for inpatient **admission** occurs.

IV. PROCEDURE

- A. Skin Risk Assessment:
 1. The skin risk assessment for pressure injuries must be completed upon admission, with every shift change, upon any inpatient transfer and with any change in patient condition.
 - a. The Braden scale is a nationally recognized, proven and reliable risk assessment for pressure injuries and will be used.
 - b. Interventions are planned and implemented based on risk level.

2. Inpatient skin risk assessment is to be completed with each shift.

3a. For all skin injuries, the RN is required to photograph the locations of skin breakdown on the Wound Assessment and Photography form (Form 152-7351-301B) and assess and document the need for assistive devices including wound VAC (vacuum assisted closure) and air flow mattresses.

- a. Utilize the “Skin/Braden Risk Assessment Tool” for assistance in specialty bed selection.
- b. An Event Report is to be completed for all acquired pressure injuries including pre- existing wounds that worsen or fail to improve.

Policy Title	Pressure Ulcer/Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
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- c. Thorough documentation of the pressure injury assessment including shall include photography of all wounds at Stage II and above any abnormality, and PRN, whether hospital acquired or pre-existing, as part of documentation of clinical condition on admission or separately.
- 43. A two-nurse skin check is to be performed on admission, every concurrent shift, on transfers to other units, all transfers to other units, and with changes in patient condition.
- 5. Licensed Respiratory Care Practitioner (RCP) shall assess skin integrity when patient is receiving ventilation or oxygen therapy.

B. Interventions Based on Braden Assessment Score:

1. Mild Risk (15 or greater per Braden Assessment Scale)
 - Bathe daily with mild soap, rinse and dry thoroughly
 - Keep skin clean, dry and free of body wastes, perspiration and wound drainage
 - Use moisturizer for dry skin
 - Do not massage bony prominences
 - Protect skin from moisture with under pads and use a barrier cream or ointment to perineal area of incontinent patients.
 - Reposition a minimum of every 2 hours and document
 - Inspect skin daily for signs and symptoms of breakdown; note any changes from admission assessment and contact wound care RN for evaluation.
 - Do not pad the bed with excessive linen, and do not use plastic linen devices next to the skin (plastic diapers, etc)
2. Moderate to High Risk (14 or less per Braden Assessment Scale)
 - All interventions for Mild Risk should be in place and followed in addition to the following:
 - Request skin/wound consult
 - Request nutritional consult. Nutrition to consult with the physician for dietary interventions.
 - Obtain physical therapy consult. Physical therapist to consult with the physician for mobility, pressure relieving devices and or activity interventions
 - Utilize pressure relieving devices including air mattress or overly, elbow and heel protectors. See Skin/Braden assessment algorithm for details.
 - To prevent friction related tissue damage, 2 people should lift the patient with a draw sheet, when moving from one surface to another or up in bed. Do not drag the patient. An overhead trapeze can be added for the patient to assist. When repositioning the patient, make sure all tubes are out from under the patient. Place a soft pillow between the legs. Since shearing forces tribute to breakdown, patients should be prevented from sliding down in bed. Head of bed is to be kept flat or elevated less than 30 degrees and it knees slightly elevated slightly, unless medically contraindicated an except at mealtimes.
 - Patient and family education to include all the above interventions.

C. Incident Reporting of Acquired Pressure Injuries:

1. All pressure injuries are to be color photographed upon admission by the admitting RN and on Mondays and Thursdays by the certified wound nurse.

- a. The photo should be placed on form 152-7351-301B "Wound Assessment and Photography" and placed in the patient's chart.
- b. All parts of the form must be completed and signed by the RN completing the form.

Policy Title	Pressure Ulcer/Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
---------------------	--	-----------------	---------

2. An event report will be completed on all acquired skin breakdown or pressure injuries that occurred while the patient is in the hospital or an existing wound present on admission which fails to respond to treatment and advances or worsens.
3. Pressure Injury/Assessment
 - a. All pressure injuries should be color photographed by the [certified wound nursePrimary Nurse and Certified Wound Nurse](#).
 - b. Research indicates that there are several stages to the severity and condition of pressure injuries.
 - c. Treatment of these injuries must acknowledge these differing stages.
 - d. The following [section \(D: Staging of Pressure Injuries\)](#) identifies stages ~~are as~~ adapted from the National Pressure Injury Advisory Panel, 2016 revised pressure injury staging.

D. Staging of Pressure Injuries:

1. **STAGE 1 PRESSURE INJURY:** Non-blanchable erythema of intact skin Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.
2. **STAGE 2 PRESSURE INJURY:** Partial-thickness skin loss with exposed dermis Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARS), or traumatic wounds (skin tears, burns, abrasions).
3. **STAGE 3 PRESSURE INJURY:** Full-thickness skin loss Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.
4. **STAGE 4 PRESSURE INJURY:** Full-thickness loss of skin and tissue Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Policy Title	Pressure Ulcer/Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
---------------------	--	-----------------	---------

5. **UNSTAGEABLE PRESSURE INJURY:** Obscured full-thickness skin and tissue loss Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be softened or removed.
6. **DEEP TISSUE PRESSURE INJURY:** Persistent non-blanchable deep red, maroon, or purple discoloration Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle, or underlying structure are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.
7. **MUCOSAL MEMBRANE PRESSURE INJURY:** Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. These ulcers cannot be staged.

E. Documentation Requirements:

1. The Patient Admission Database must be completed for all admitted patients
2. Braden scale upon admission, with every shift,
3. Skin assessment- on admission, ~~every concurrent shift,~~ upon transfers, and with change in patient condition.
4. Wound assessment and photograph (form 152-735-301B) will be completed for any wounds present and placed in the patient's chart.
5. Document all dressing changes in nursing notes.
6. Complete an event report for pressure injuries that are acquired during the hospitalization.
7. RCP will document skin integrity and barrier change and/or cleaning, if applicable.
 - a. If assessment of skin integrity is not possible due to patient condition and/or behavior, reason for inability to provide assessment will be documented.

F. Nursing Education:

1. Chart audits and review of all incident reports related to wound care policy will be conducted in a scheduled basis and reported to the quality manager.

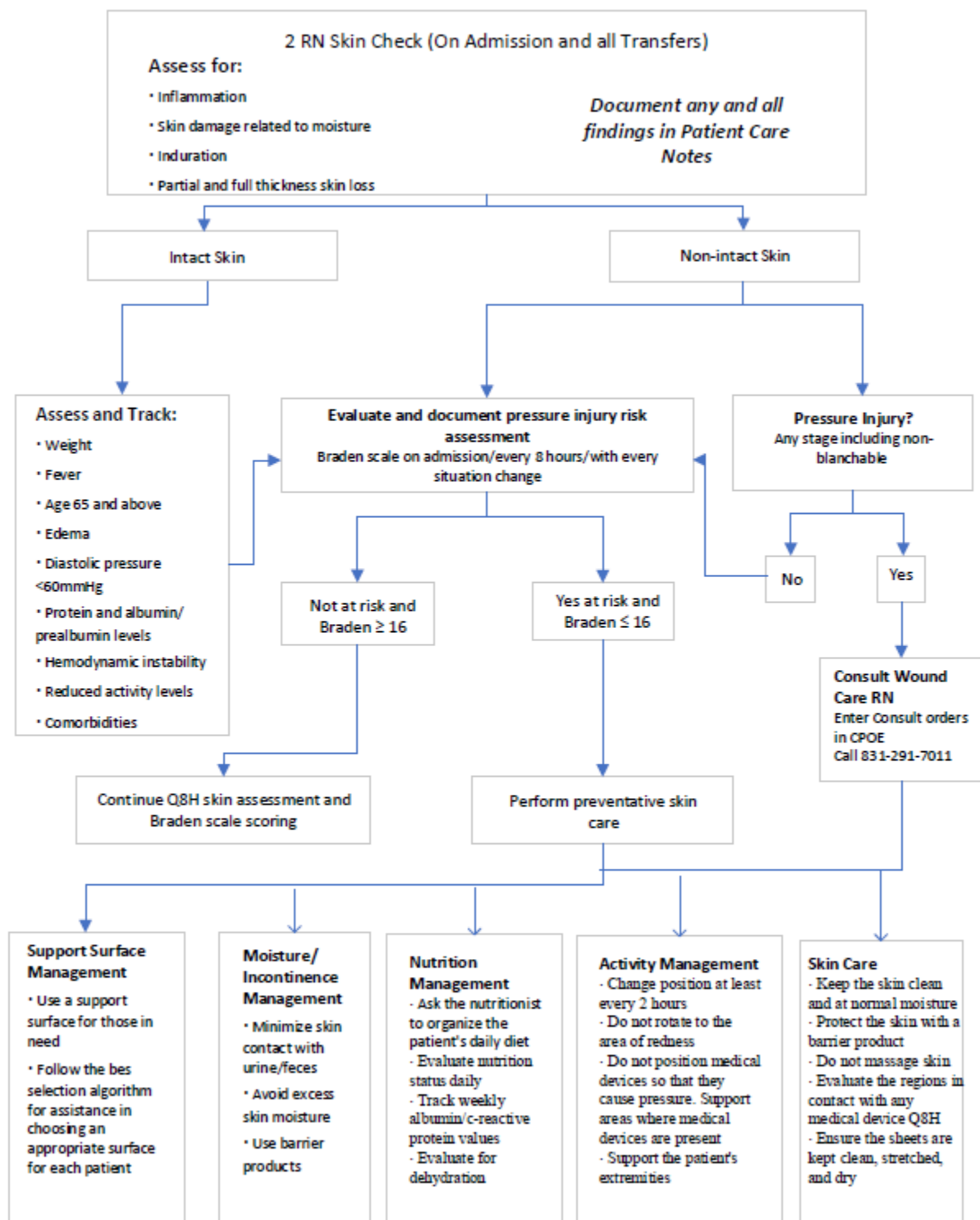
V. REFERENCES

- Padula, W.V. and Black, J.M. (2019), The Standardized Pressure Injury Prevention Protocol for improving nursing compliance with best practice guidelines. J Clin Nurs, 28: 367-371. doi:10.1111/jocn.14691
- Tuba Yilmazer, PhD, RN and Hulya Bulut, PhD, RN. Published in Wound Care Journal, 2019 Vol 32 No 6
- Updated staging system 2016, National Pressure Injury Advisory Panel Retrieved at web site. Updated Staging System 2016, www.npuap.org

VI. STAKEHOLDERS

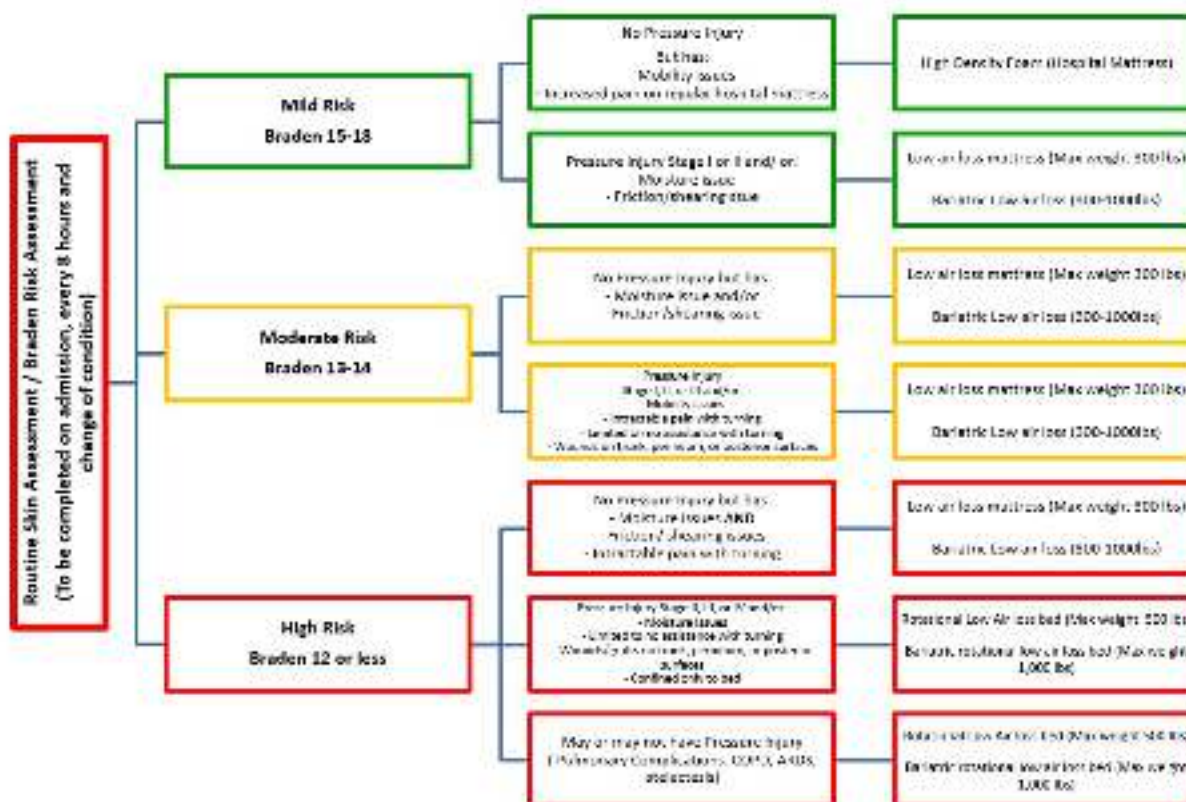
Policy Title	Pressure Ulcer/Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
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ATTACHMENTS



Policy Title	Pressure Ulcer/Prevention/Management (Wound Risk Assessment)	Policy #	NUR1986
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Skin/Braden Risk Assessment Tool



Policy Title	EC.02.06.05.02.g Hot Work Permit Policy	Policy #	EC.02.06.05.2.g
Responsible	Facilities Department	Revised/Reviewed	11/2022

I. PURPOSE

Manage any operation involving open flames or heat/sparks.

II. POLICY

It is the policy of Watsonville Community Hospital to manage all construction, renovation, modernization and structural repairs in a manner designed to minimize the potential for open flames or fire due to construction operations. Watsonville Community Hospital uses FM Global's Hot work Permit System for managing any operation involving open flames or producing heat/sparks. This includes, but is not limited to: brazing, cutting, grinding, soldering, and torch applied roofing and welding. The Hot Work Permit System Wall Kit is located in the Engineering shop.

III. DEFINITIONS

Definitions if needed

IV. PROCEDURE

Procedure details

1. The Safety Officer or designee shall verify the required precautions on the hot work permit.
2. The Safety Officer or designee will complete and retain Part One of the permit and issue Part Two to the person(s) doing the work.
3. Permits are required for both contractors and hospital employees and this is to be indicated on the permit.
4. Date, Location, Nature of Job, Expiration, and person completing the work shall be listed on the permit as outlined.
5. No permit shall be issued when the required precautions checklist cannot be completed in its entirety.
6. All permits require the signature of the Safety Officer or designee.
7. A Copy of the permit shall be posted in the area where the work is being completed and returned to the Safety Officer or designee when all requirements of the permit have been satisfied.

V. REFERENCES

References used

VI. STAKEHOLDERS

If applicable

Policy Title	Massive Transfusion Protocol	Policy #	XXXXX
Responsible	Emergency Department, Labor & Delivery, Intensive Care Unit, Special Procedures, Operating Room, Pediatrics, Anesthesia, Laboratory.	Revised/Reviewed	2/23/2023

I. PURPOSE

- A. Provision of a standard for the activation and administration of an MTP (Massive Transfusion Protocol) for rapid distribution of blood products for patients with massive hemorrhage. MTPs are a designed system of locally agreed and specific guidelines to mitigate the triad of acidosis, hypothermia and coagulopathy of hemorrhagic shock.

II. POLICY

- A. A Provider may choose to request 1-2 units of Emergency Release blood while assessing the need for an MTP. To do so, the Provider will:
 1. Complete the form Emergency Release for Uncrossmatched O Blood.
 2. Call the Blood Bank at extension x1059 with the verbal request and patient sex.
 3. Send a runner to the Blood Bank for immediate pick-up with the yellow copy of the Emergency Release Form.
- B. Consider MTP if there is an expected need of greater than two (2) Emergency Release pRBCs (packed Red Blood Cells) or more than ten (10) cross-matched units in 24 hours.
- C. A Provider may activate the MTP as indicated, including:
 1. Emergency Department patient with penetrating or blunt trauma, GI bleed, aortic dissection, etc.
 2. Obstetrics patient with Cesarean section complications, postpartum hemorrhage, etc.
 3. Special Procedure patient with GI bleed, complications of colonoscopy, interventional procedure, etc.
 4. Surgical patient with complications from surgical procedure, etc.
 5. ICU patient with hemorrhagic shock, GI bleed, post-surgical bleed, DIC, etc.
 6. Pediatric patient with penetrating trauma, GI bleed, etc.
 7. Deviations from protocol may occur at Provider discretion and are to be documented by the associated units.
- D. When MTP is activated, blood products are released as a complete package and should not be modified.
- E. Providers and the Blood Bank coordinate to ensure judicious use of blood components.
- F. Blood Bank technicians ensure best practice of preparation, inspection, and processing of blood products for prompt and efficient release.
- G. Blood product shortages are communicated to the various department chairs in a timely manner for information distribution to all providers.
- H. Blood Bank is required to collect an initial sample for blood type and antibody screen at or prior to transfusion. Additional samples, e.g. blood type confirmation, hemograms, are essential throughout the MTP to assess hemostasis.

Policy Title	Massive Transfusion Protocol	Policy #	XXXX
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III. DEFINITIONS

- A. Emergency Release is a release of universal product (1-2 units pRBC, type O) for rapid administration prior to blood type and antibody screen completion.
1. Pediatric Emergency Release is the rapid release of 1 unit pRBC, type O, irradiated, CMV seronegative. A 'Pedi-pack' will be pre-filtered by the Blood Bank for the requested volume.
 2. The Pediatrician or Neonatologists will consult with the Laboratory Pathologist if deviating from the expected type O, CMV-negative, irradiated, filtered 'Pedi-pack.'
- B. Massive Hemorrhage may include tachycardia, palpitations, tachypnea, pallor, hypotension, reduced arterial pressure and urinary output, acidosis, coagulopathy.
1. Blood loss is calculated as % of TBV, total blood volume, or estimated volume:

Figure 1. Hemorrhagic Shock Classification

PATIENT TYPE	CLASS	BLOOD LOSS	CLINICAL SEVERITY
Adult ¹	Class I	Up to 15% TBV	Mild
	Class II	15-30% TBV	Mild
	Class III	30-40% TBV	Moderate
	Class IV	>40% TBV	Severe
Postpartum	Vaginal	>500 mL	Hemodynamic instability with any volume loss.
	C-section	>1000 mL	

- C. MTP (Adult Massive Transfusion) is the expected need of more than 10 blood products in 24 hours.
- D. pedMTP (Pediatric Massive Transfusion) is the expected administration of more than 20 mL/kg pRBC in the first hour of resuscitation, or an expected need of greater than 0.1 units/kg pRBC within the first 12 hours of resuscitation.
- E. pRBC (packed Red Blood Cells) is one unit of concentrated red blood cells of a specific blood type.
- F. FFP (Fresh Frozen Plasma) is one unit of plasma substrate.
- G. Platelets is one unit of concentrated pooled platelets from 4-6 donors.
- H. Pediatric is defined as a person less than 12 years of age or less than 50 kilograms.
- I. Neonatal is defined as birth-28 days of life.
- J. MTP Cooler is the prepared component therapy into a transportable cooler to the patient.
1. Adult MTP components (patient > 50 kg):
 - a) 4 units pRBC.
 - b) 4 units of FFP.
 - c) 1 unit of pooled platelets (store at room temperature).
 2. Modified MTP components:
 - a) 2 units pRBC.
 - b) 2 units of FFP.
 - c) 1 unit of pooled platelets (store at room temperature).
 3. Ped MTP components (patient < 50 kg):
 - a) 10-15 mL/kg of pRBC (Blood type O or type-specific).
 - b) 10-15 mL/kg of FFP.
 - c) 5-10 mL/kg of pooled platelets (store at room temperature).

Policy Title	Massive Transfusion Protocol	Policy #	XXXX
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IV. PROCEDURES

Table 1. MTP Initiation

	ROLE	EXPECTED RESPONSE – 5 MINUTES
A	Provider	<ol style="list-style-type: none"> 1. Identify patient in need of MTP. 2. Enter electronic MTP order set or MTP verbal order to Nurse. 3. Notify potential medical staff consults: Anesthesiologist, Pediatrician, Cardiology, Radiologist, Surgeon, Intensivist, O.R., Pathologist, etc
B	Nurse	<ol style="list-style-type: none"> 1. Place MedHost order for MTP. 2. Track blood product order(s) via MedHost or Blood Product Transfusion Physician Order (Form 1522-7060-31). 3. Identify a Runner for the Blood Bank cooler(s).
C	Unit Clerk	<ol style="list-style-type: none"> 1. Call Operator to activate MTP via overhead page “Massive Transfusion, Location, Bed #.”
D	Blood Bank	<ol style="list-style-type: none"> 1. Prepare MTP cooler for transport. <ol style="list-style-type: none"> a. Males, Females >age 55: O positive. b. Females, reproductive potential: O negative. c. All patients: Group A plasma. d. Switch to ABO type-specific pRBCs ASAP. 2. Communicate any potential concerns to Nurse and Pathologist.
E	Phlebotomist	<ol style="list-style-type: none"> 1. Collect ‘rainbow’ blood samples, deliver to Lab for testing. Phlebotomy will not wait for a line to be placed.
F	Respiratory Therapist	<ol style="list-style-type: none"> 1. Report for airway support. 2. Obtain blood gas sample if ordered by provider.
G	House Supervisor	<ol style="list-style-type: none"> 1. Obtain rapid transfuser. 2. Coordinate patient transfer to MTP location: <ol style="list-style-type: none"> a. Special procedure – to ED. b. Med-surg or Telemetry – to ICU. c. OB, OR – to ICU. 3. Plan for if patient transfer to outside hospital for definitive management.
H	Runner	<ol style="list-style-type: none"> 1. Report to Nurse to receive blood product orders. 2. Obtain patient demographic label for delivery to Blood Bank.

Policy Title	Massive Transfusion Protocol	Policy #	XXXX
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Table 2. MTP Ongoing

	ROLE	ONGOING TASKS
A	Provider	<ol style="list-style-type: none"> 1. Communicate challenges, completion of tasks with nursing, consults. 2. Ensure documentation of details for blood product administration.
B	Nurse	<ol style="list-style-type: none"> 1. Obtain 2 large-bore IVs \geq 18-gauge for large volume rapid infusion. 2. Set up level 1 or Belmont transfuser to warm blood prior to administration. 3. Collect Laboratory samples at the end of each shipment (blue, purple, gold). 4. Maintain normothermia with ambient temperature control and Bair Huggers. 5. Administer blood products to the patient in the fastest, safest manner. <ol style="list-style-type: none"> a. Repeat back patient identifiers. b. Repeat back blood product identification.
C	Unit Clerk	<ol style="list-style-type: none"> 1. Assist with contacting additional providers, department heads.
D	Blood Bank	<ol style="list-style-type: none"> 1. Prepare additional MTP cooler for transport. 2. Track all products leaving the Laboratory. 3. Contact Red Cross for additional blood products as necessary. 4. Communicate challenges, delays, and product shortages promptly. <ol style="list-style-type: none"> a. 20 minutes to thaw FFP.
E	Phlebotomist	<ol style="list-style-type: none"> 1. Collect appropriate blood samples from nurse, deliver to Lab for testing. 2. Act as a Runner if needed.
F	Respiratory Therapist	<ol style="list-style-type: none"> 1. Continue airway and blood gas support.
G	House Supervisor	<ol style="list-style-type: none"> 1. Continue coordination of care.
H	Runner	<p>At each cooler delivery:</p> <ol style="list-style-type: none"> 1. State patient name, gender, blood type in cooler. 2. Ask provider: "Continue, Stop, or Hold?"

I. Other adjunct therapies and resuscitation measures:

Place appropriate large bore IV catheter.

Avoid hypothermia.

Avoid hypocalcemia.

Avoid acidosis.

Minimize crystalloid administration.

Consider hemostasis in all patients.

Consider reversal of anticoagulants.

Consider TXA in trauma or OB patients.

Consider cryoprecipitate order to Red Cross.

Policy Title	Massive Transfusion Protocol	Policy #	XXXX
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Table 3. MTP Cessation

	ROLE	CESSATION TASKS
A	Physician	1. Deactivate MTP. Notify Nurse, House Supervisor, Med Staff Consults. 2. Sign all orders, i.e. Emergency Release, Blood product orders, Transfusion orders, etc.
B	Nurse	1. Notify Blood Bank, state if there are blood products to be returned. 2. Determine if blood samples are needed to assess hemostasis.
C	Blood Bank	1. Immediately reconcile all products issued and returned. 2. Determine if products can be returned to storage vs. wastage. Document.
D	Phlebotomist	1. Assist with tracking and return of all blood products.
E	Respiratory Therapist	1. Support respiratory needs as necessary.
F	House Supervisor	1. Transfer patient to appropriate location for ongoing resuscitation when stable.
G	Runner	Return all unused products to Laboratory Blood Bank ASAP to prevent waste: 1. pRBC on ice packs. 2. Platelets at room temp!

V. REFERENCES

1. ATLS Classification of Hemorrhagic Shock. December, 2021.
2. AAST. American Association for the Surgery of Trauma. Safety of the Use of group A Plasma in Trauma: the STAT Study. Nancy M. Dunbar and Mark H. Yazer, Biomedical Excellence for Safer Transfusion (BEST) Collaborative. Transfusion 2017;57 ;1879-1884.
3. Evangelista ME, Gaffley M, Neff LP. Massive Transfusion Protocols for Pediatric Patients: Current Perspectives. J Blood Med. 2020;11:163-172 <https://doi.org/10.2147/JBM.S205132>.
4. MTP Policy Benchmarks: Natividad Trauma Center, UCSF, Stanford, Regional Medical Center.
5. EM Crit: <https://emcrit.org/ibcc/mtp/> . Internet Book of Critical Care. Accessed 2.16.2023.
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7. Jennings LK, Watson S. Massive Transfusion. [Updated 2022 Aug 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK499929/>

VI. ATTACHMENTS

1. Adult Blood Product Transfusion Physician Orders. Form 152-7060-31.
2. Emergency Release for Uncrossmatched O Negative Blood. Form 152-6133-01.
3. Blood Transfusion Consent. Form 152-7060-100.

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU		
Policy/Procedure #	2240	Effective	10/93	Page	1 of 6
Department Generating Policy	Surgery	Revised	12/12		
Jane Winning		Dept/Title	Surgical Services Director		
Cheryl Moore		Dept/Title	Director Laboratory Svcs		
Jennifer Gavin		Dept/Title	Pharmacy Director		
Cheryl Richardson		Dept/Title	Infection Preventionist		
Sherri Stout-Torres		Dept/Title	CNO		
Donna Salvi		Dept/Title	CQO		
Audra Earle		Dept/Title	CEO		
B&T: Paula Quinn, MD		Dept/Title	Chair		

I. PURPOSE:

To ensure the proper use of the Rapid Autologous Transfusion System (RATS). To ensure patient safety.

II. POLICY:

A autologous blood recovery system which collects blood, concentrates and washes the red blood cells. It is indicated for use for processing:

Blood shed by a patient during surgery;
 Blood collected preoperatively from trauma patients (e.g., traumatic hemothorax);
 Blood collected postoperatively from chest or wound drains
 Blood collected for the purpose of autologous platelet rich plasma.

The Rapid Autologous Transfusion System will be used on the order of the physician. Operators will be aware of the manufacturer's suggestion regarding contraindications. Each operator will complete the competency review checklist, review policy and procedure, and perform a demonstration of the system if the operator has not actually used the equipment during the period, bi-annually in April and October.

III. PROCEDURE:

- A. Obtain informed consent from the patient for cell salvage. This is included on the back of the transfusion consent.
- B. All operators will know the contraindications as stated by the manufacturer and rationale thereof. These contraindications include:
 1. Use of the Rapid Autologous Transfusion System in the presence of amniotic fluid.
 - a. Effect: Contains proteolytic enzymes which could activate clotting.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM.
 2. Fecal Contamination
 - a. Effect: Sepsis

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU
Policy/Procedure #	2240	Page	2 of 6

- b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. Aspiration may be necessary in emergency cases. The use of the Rapid Autologous Transfusion System in these situations is left to physician's discretion.
3. Use of the RATS in the presence of tumor cells.
 - a. Effect: Potential of metastasis not well studied. Use of autologous blood, however, reduces exposure to homologous blood products and the potential of suppression.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. Aspiration may be necessary in emergency cases. Use of the RATS in these situations is left to the physician's discretion.
4. Use of the RATS in the presence of clotting adjunct (monofilament collagen, topical thrombin).
 - a. Effect: May activate clotting.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate wound before resuming salvage.**
5. Use of the RATS in the presence of Betadine.
 - a. Effect: Reduces hemoglobin (seems to be a reversible effect). May cause allergic reaction if patient sensitive to iodine.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate wound before resuming salvage. Thorough wash of salvaged blood.**
6. Use of the RATS in the presence of Fibrin Glue Thrombin.
 - a. Effect: May activate clotting.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate before resuming salvage.**
7. Use of the RATS in the presence of Avitene.
 - a. Effect: Platelet Activation.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM.
8. Use of the RATS in the presence of Methyl Methacrylate
 - a. Effect: Toxicity, heat produced hemolysis.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate before resuming salvage.**
9. Use of the RATS in the presence of gastric fluids.
 - a. Effect: Proteolytic enzymes - may cause clotting activation.
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate before resuming salvage.**
10. Use of the RATS in the presence of antibiotics not licensed for parenteral use (e.g., Polymyxin Aminoglycosides).
 - a. Effect: Potential for serious reaction; may be delivered in higher concentrations (e.g., hypotension, shock).
 - b. Recommended Action: DO NOT ASPIRATE INTO SYSTEM. **Irrigate wound copiously with saline before resuming salvage.**

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU
Policy/Procedure #	2240	Page	3 of 6

C. RATS System Set-Up

1. Prepare Anticoagulant Solution
 - a. Heparin concentration will be 30,000 units to 1000ml 0.9% NaCl.
 - b. Medication added labels will be affixed to the anticoagulant.
 - c. Heparin shall be used 1:7 with blood loss.
 - d. Gentle agitation of reservoir during the procedure is required depending on blood loss.
 - e. Amount of anticoagulant used will be documented on operator flow sheet.
2. Collection System
 - a. Place reservoir holder and receive split of suction assembly from the sterile field. Attach and close reservoir outlet clamp.
 - b. Connect suction assembly large bore tubing (blue cap) to inlet port (blue cap) on reservoir. Tighten down extra inlet caps.
 - c. Connect vacuum line to vacuum port on reservoir and regulate vacuum to 100-150 mmHg.
 - d. Spike anticoagulant solution with small bore tubing of the suction assembly and allow 150-200ml of anticoagulant solution to enter reservoir.
 - e. Use return option to agitate blood in reservoir periodically.
3. RATS Pack Tubing System
 - a. Lift centrifuge cover. Release hold-down locking mechanism and slide hold-down arm to open position.
 - b. Open RATS PAK and remove reinfusion bag. Hang from upper arm of IV pole. **Do not** close clamps on bag. Hang wash solution (3L IV 0.9% NaCl) from second IV pole.
 - c. Insert centrifuge bowl into turn bowl by aligning slots on side of bowl with three locking pins in turn table. Push bowl straight down until it stops, and then turn clockwise to lock under pins.
 - d. Rotate by sliding hold down arm over lip of bowl. Arm should fit flush on top of bowl.
 - e. Route tubing from lower port on bowl out through the notch in the right side of centrifuge well to the waste bag. Close slide clamp on waste bag and hang on three hooks on right side of machine.
 - f. Route tubing from upper port on bowl through notch in left side of centrifuge well to roller pump.
 - g. Lift roller pump cover and insert tubing firmly into process fluid sensor. Be sure it is pushed in securely.
 - h. Route tubing through roller pump.
 - i. Insert trifurcation assembly into holder on top of machine.
 - j. Open valves by pressing down gently on valve top and swinging locking arm away from the top. Route appropriate color coded tubings through valves and close valve covers.

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU
Policy/Procedure #	2240	Page	4 of 6

- k. Connect red tubing to collection reservoir drain port.
- l. Connect yellow tubing to saline wash solution.
- m. Connect blue tubing to "crit line" sensor and then connect to reinfusion bag center port.

D. Processing

1. Power on the RATS system. Choose protocol to be used. Present default is ORTHO protocol which we mainly use.
2. Manual Mode:
 - a. Fill
 - (1) Select fill when fluid level in reservoir reaches:
 - (a) 600-1000ml if using standard volume bowl.
 - (b) 450-600ml if using low volume bowl.
 - (2) Allow bowl to fill until red cell interface reaches mark on metal bar inside the centrifuge bowl (hematocrit will be between 50-60% in the standard bowl and between 45-50% in the low volume bowl).
 - b. Wash
 - (1) Select "wash" when centrifuge bowl is properly filled.
 - (2) Allow minimum one liter. Salinewash. Grossly hemolyzed blood and bowls that are not completely filled will require more volume. **Use minimum 1500ml wash for orthopedic cases.** Continue to wash cells until line from centrifuge bowl to waste bag is crystal clear and the minimum one liter wash has occurred.
 - c. Empty
 - (1) Select "empty" when wash cycle is complete.
3. Automatic Mode

Select AUTO when fluid level in reservoir reaches 600-1000ml. RATS will automatically fill bowl to appropriate hematocrit level, then wash with one liter saline and empty into reinfusion bag. The fill cycle should be monitored to avoid premature triggering of the wash cycle caused by grossly hemolyzed blood.
4. Use Concentrate option to bring blood from holding bag back to bowl when adequate amount isn't available in reservoir to process subsequent bowl. Press concentrate under special key.

E. Reinfusion

1. After the blood processing is completed the washed packed red blood cells in the reinfusion bag will be available for reinfusion. Press Purge from Special Option. Invert bag, press pump and hold until air is purged from bag. Press Tally to show volume of RBCs and Hct. Press print. Blood will be reinfused only in the operating room and recovery room. Blood will be given to the anesthesia staff for reinfusion. A Hct >45 is needed to reinfuse. For policy on adverse reactions to blood reinfusion please refer to Blood Administration policy.
 - a. Reinfusion bags not connected to the RATS will be labeled with appropriate label and marked with expiration time (six hours after recovery) and Biohazard Label.

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU
Policy/Procedure #	2240	Page	5 of 6

- b. The unit of processed blood will be given to the anesthesiologist for reinfusion.
- c. A 20-40 micro aggregate filter (Pall filter) will be used in accordance with the manufacturer's suggestion.
- d. Time of reinfusion will be documented on the Operator's Flow Sheet.

F. Orthopedic Procedures

1. When assembling supplies for an IAT procedure, substitute the "low volume bowl" for the standard volume bowl.
2. Use Ortho Protocol.
Note: Processing in the manual mode will prevent the possible premature triggering of the red cell detector caused by gross hemolysis of the blood in the collection reservoir.
3. Avoid aspiration into the collection reservoir of potentially harmful substances (refer to the Substances and Effects Table).
4. Avoid processing "partially filled" bowls of collected blood.
5. Use a minimum 1500ml wash volume; however, continue to wash until the waste line is clear.
6. After pumping the washed blood into the reinfusion bag, allow the red blood cells to "settle" before beginning reinfusion. This will allow visualization of any fat particles.
7. If fat particles are present, re-process by entering the concentrate mode and re-wash with an additional 1500ml of saline. During this re-wash, change the reinfusion bag to avoid pumping the red blood cells back into a bag coated with "fat."
8. All salvaged blood should be returned to the patient through a 20-40 **micro aggregate filter**.

G. Cleanup and Documentation

1. Print your tally report.
2. Push unload to release the pump tubing. Push shutdown. Turn off machine.
3. Dispose of bags and tubing in Biohazard bags.
4. Change suction tubing each case to ensure clean tip.
5. Wipe down with disinfectant after covering air detector.
6. Make two copies of RATS record one for Recovery Room records, one to blood bank and original to chart

IV. **QUALITY REVIEW PROGRAM**

- A. This will consist of a quarterly review of all cases in which the cell saver was used. The review will focus on the EBL, amount of blood reinfused, and the HCT of the reinfused product. The machine generated HCT will be verified by a laboratory HCT during or after the procedure. If multiple bowls are reinfused, this HCT check will only be performed once during the entire procedure. The values should correlate within a 5% range. This review will occur in the Operative and Invasive Procedures Committee.

Policy/Procedure Title	Rapid Autologous Transfusion System	Manual Location	PACU
Policy/Procedure #	2240	Page	6 of 6

Reviewed:

	1st	2nd	3rd	4th	5th
Date:	3/97	3/01	2/04	9/05	10/06
By:	_____	_____	_____	_____	_____

Revised:

	6th	7th	8th	9th	10th
Date:	03/10	_____	_____	_____	_____
By:	J. Winning	_____	_____	_____	_____

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
Responsible	Laboratory Director	Revised/Reviewed	<u>10/19/2022</u> 09/2020

I. PURPOSE

The antibody screen is used to detect unexpected blood group antibodies. In the gel test, the reagent red blood cells are combined with sample plasma in the upper reaction chamber of the microtube of an MTS Anti-IgG card. Following incubation period to enhance antigen/antibody interaction, the sensitized red blood cells react with the Anti-IgG incorporated in the gel of the microtube during a centrifugation step. Agglutination indicates the presence of an antigen/antibody reaction while lack of agglutination indicates the absence of an antigen/antibody reaction. Agglutinated red blood cells become trapped in the gel at various levels within the microtube, depending on the size of the agglutinates. Free nonagglutinated red blood cells pass through the gel and form a button of red blood cells on the bottom of the microtube.

II. POLICY

When a "type and screen" is ordered, the screen portion, or indirect antibody test is performed using the Ortho-Diagnostic ID-Micro Typing System. An anti-human globulin anti IgG (rabbit) MTS Gel Card is used with patient's plasma and each of the three screening cells in the Surgiscreen testing kit, and incubated for 15 in a 37 degree MTS Incubator. Surgiscreen is composed of human red blood cells in a 0.8% ready to use form. The entire card is then centrifuged in the MTS Centrifuge for 10 minutes and then visually read and interpreted. If the interpretation is of mixed field or indeterminate, a follow up tube screen and/or referral to ARC Reference Laboratory will be instigated.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Specimen

1. Edta whole blood correctly labeled, less than 72 hours old.
2. Specimens must be completely, accurately and legibly labeled.
3. The date, time of draw, BB ID, MR, complete name and date of birth must be on the specimen, as well as the phlebotomist who drew the blood.
4. Hemolyzed samples may only be used if a redraw of the patient is not possible or the delay could cause harm to the patient. Care should be taken to interpret a hemolyzed specimen. Comparison of pre and post plasma color should be made to rule out a hemolytic reaction.
5. Icterus or lipemia may also be difficult to interpret. Grossly lipemic samples may contain particulates that clog the gel, as indicated by diffuse blotches of red blood cells in the tube.

B. Reagents, Supplies, and Equipment

1. Bring all reagents to room temperature.(18-25 C)
2. Reagents : MTS Anti-IgG Gel card (keep upright)
3. Antibody screen cells – Surgiscreen three cell testing
4. Working reagent- aliquot surgiscreen cells for daily testing. Save unused bottle in refrigerator inside box to avoid light exposure. Aliquot only the volume expected to be

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
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used that shift into the working reagent bottle, return to refrigerator when not in use. Add fresh surgiscreen from original bottle only as needed. Mix well before aliquoting.

5. MTS 2 Diluent used to dilute red cells for an auto control
 6. Tipmaster pipette and Tips
 7. MTS Incubator
 8. MTS Centrifuge
- C. Gel Cards Preparation
1. Do not use gel cards if the gel is absent or the liquid level in the microtube is at or below the top of the gel matrix. The microtube should have a clear liquid layer on top of opaque gel.
 2. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals or other artifacts.
 3. Do not use cards that have failed visual inspection.
 4. Do not use cards if foil seals appear damaged or opened.
 5. Do not use gel cards that were not shipped in an upright position.
 6. Store cards at 2 degrees C to 25 degrees C. (36-77 degrees F)
- D. Procedure
1. Holding the card upright, mark off three microtubes with a pen, this is needed for each of the three Surgiscreen cells.
 2. Label each triplet with the patient's last name and BB ID or MR if no BB ID available. Check to make sure the identification matches the tube itself.
 3. Remove the foil seal from the microtubes to be used. Visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.
 4. Do not remove the foil until ready to use. Foil should be removed immediately before testing or within 1 hour of testing.
 5. Do not use gel cards that have not been shipped or stored in an upright position.
 6. Using the Tipmaster pipette, add 50 uL of each of the three Surgiscreen cell suspensions into the labeled microtubes. Screen 1, 2 and 3 into each consecutive tube.
 7. The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.
 8. Using the Tipmaster pipette, add 25 uL of patient plasma to the labeled microtubes. This mixture may or may not touch the gel suspension.
 9. Place in MTS Incubator slot, close cover and incubate at 37 degrees C(+/- 2 degrees) for 15 minutes (maximum 40 minutes)
 10. Antibodies all react best at different conditions, no single test method will detect all antibodies.
 11. Centrifuge the gel at the preset conditions (875 rpm for 10 minutes)
 12. Read the front and the back of each microtube macroscopically. No aid other than light is to be used in reading.
- E. Interpretation
- Grading Gel Test Reactions**
1. Negative No agglutination and no hemolysis of the red blood cells is a negative test result. The unagglutinated red blood cells pass through the gel and form a well defined button of red blood cells on the bottom of the microtube.
 2. 1+ Positive Agglutination and or hemolysis of the red blood cells is a positive test result. For the 1+ positive test the agglutinated red blood cells are observed predominantly in the lower half of the gel microtube. Unagglutinated red blood cells form a button on the bottom of the microtube.

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
---------------------	---	-----------------	--------

3. 2+ Positive Agglutinated red blood cells are dispersed throughout the length of the gel microtube. A few unagglutinated red blood cells may be observed in the bottom of the microtube.
 4. 3+ Positive The majority of agglutinated red blood cells are trapped in the upper half of the gel microtube.
 5. 4+ Positive Solid band of red cell agglutinates on top of the gel. A few agglutinates may filter into the gel but remain near the predominant band.
 6. Mixed field Agglutinated red blood cells at the top of the gel or dispersed throughout the gel microtube accompanied by a button of negative red blood in the bottom of the microtube. Caution must be taken in interpreting a reaction as mixed field. Additional patient history and testing will be necessary for resolution.
- F. Computer Entry
1. Negative results- No agglutination and no hemolysis of the red blood cells is a negative result. All the red cells will be at the bottom of the microtube in a well delineated pellet.
 2. Positive result- agglutination and/or hemolysis of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions. Grade the positive reaction from 1-4 as positive, and 0 as negative.
 3. A mixed field reaction is characterized by a band of red cell agglutinates on top of the gel, accompanied by a pellet of unagglutinated cells at the bottom of the microtube. Mixed field reactions shall be graded as "mixed field" in the Scrn 1,2,3 place under test results. NO INTERPRETATION IS MADE IN THE WYNDGATE. Once the results are entered as mixed field, save and cancel the gel antibody screen, then reorder and perform a tube antibody screen. (If an interpretation is placed in the far left field under "interpretation" you will not be able to cancel the test.) "Mixed field" results should not be reported on the final report. If results are not negative in the tube screen, investigate the cause of the mixed field. Cold agglutinins, loose fibrin (recentrifugation of the specimen may be considered) positive dat, positive autocontrol, alloantibodies, autoantibodies are to be considered. If unresolved, send to Reference Laboratory.
 4. Interpretation of mixed field reactions must be done with caution. The presence of fibrin, clots or particulates may result in some red blood cells to be trapped at the top of the gel. Mixed field reactions should only be observed in tests containing a dual population of red blood cells, such as a transfused patient, bone marrow recipient or when a pooled cell sample is used for testing. However, not all mixed red blood cell situation have a sufficient minor population to be detected.
 5. If results are positive, see "Antibody Identification Procedure" in how to perform
 6. an antibody panel.
- G. Limitations
1. False positive or false negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials or omission of test samples.
 2. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
 3. Red blood cells that test as DAT positive should not be used in an indirect antiglobulin procedure.
 4. Improper technique may invalidate the results obtained.
 5. False positive test results may occur if antibodies to components of the preservative solution are present in the sample tested.

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
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6. For antibody detection and identification, different serological methods are optimal for different antibodies. No single antibody screening or identification method optimally detects all anti bodies. In some low ionic strength test systems, certain Anti-E and Anti-K antibodies have been reported to be nonreactive.
7. Rouleaux cause by serum or plasma with abnormally high concentrations of protein (such as in patients with multiple myeloma or patient who received plasma expanders such as Hydroxyethyl Starch possibly given in the surgical suite) may cause false positive results.
8. The Anti- IgG cards will not detect anti-C3.
9. IgM antibodies may react in the anti- IgG card. Some IgM antibodies may be trapped in the top portion of the gel and result in a positive reaction.
10. False positive reactions may occur if the card used had showed signs of drying.
11. Anti-H of Para-Bombay specimens may not be detectable in gel.
12. Prolonged exposure of Surgiscreen cells to light sources and room temperature can cause nonspecific positive reactions. (Including light in the refrigerator.)

**minimize exposure of reagent red blood cells to light sources while in use and while being stored*

**minimize prolonged exposure to room temperature and store Surgiscreen in*

refrigerator when not in use- USE WORKING REAGENT BOTTLES

**when investigating problematic patient samples, include inquires about the use of volume expanders in the patient history.*

V. REPORTING RESULTS

- A. Computer Entry:
 1. Follow Wyndgate SafeTrace Tx "Entering Results Overview and General Instructions" #2735, 7/2010.
- B. Downtime
 1. Manually write results on log.
 2. Once system is operational, order and enter all results with correct backdating.

VI. QUALITY CONTROL

1. One positive and one negative test must be performed daily for the gel system.
2. CorQC is to be used for the positive control. This is a blend of murine/human antibodies diluted with bovine albumin in physiologic saline used to simulate the protein concentration of human serum.
3. Diluted albumin may be used for the negative control.
4. The first gel antibody screen of the day beginning at midnight will perform the quality control. Only one per day is needed unless a problem is suspected.
5. Fill in the "Gel Quality Control" worksheet.

VII. MAINTENANCE

A. Incubator

1. DAILY

Check the temperature daily.

 - a. Be sure the power switch is set to OFF.
 - b. Fill a test tube to the level of the incubator block top surface with water or saline
 - c. Place the test tube in one of the test tube areas on the sides of the incubator, Rotating the position daily, and recording the position.
 - d. Set the power switch to ON and let the incubator heat for the required 10 minutes.
 - e. Place a thermometer in the test tube and hold it there until the temperature stabilizes.

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
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- f. Record the temperature from the thermometer and verify that it is within the temperature range of 37 degrees Centrifuge +/- 2 degrees.
 - g. contact OCD customer technical service if the temperature is not within specified range (1-800-421-3311)
 - h. Rotate the position of the thermometer throughout the entire 24 positions.
2. AS NEEDED
 - a. Unplug the power cord
 - b. Clean the MTS incubator with a lint free cloth and mild detergent or water Do not use alcohol on the cover, do not immerse instrument in water, do not Pour liquid over the instrument.
3. REPLACE THE FUSE
 - a. Be sure the power switch is OFF
 - b. Disconnect the power cord from the power supply
 - c. Locate the fuse holder beside the power cord socket on the rear panel
 - d. Remove the fuse holder by inserting a small screwdriver into the slot at the bottom of the holder to pull the fuse holder out
 - e. Pull the fuse holder out and replace the fuse with a new fuse. A new fuse should be kept in the drawer bottom drawer beneath the incubator *1.0 AMP 250 VAC 5x20 mm call (biomed to see if they have any fuses this size if one is not in drawer)
 - f. Replace the fuse holder; make sure the fuse holder snaps into place
 - g. Reconnect the power cord and turn power ON

B. Centrifuge

1. DAILY
 - a. Confirm Instrument Display- visually check that the tachometer RPM display reads 895 +/- 25. Record RPM on QC daily log
 - b. Check that the timer display begins at 10:00 minutes and counts down. (9:59, 9:58...) when the timer reaches zero. The display becomes blank.
 - c. Contact OCD customer technical service if display is not functioning correctly (800-421-3311)

C. Maintenance

1. WEEKLY
 - a. Wipe down the incubator and centrifuge with a damp cloth. Use a mild detergent or 70% isopropyl alcohol.
 2. PERIODIC
 - a. Send pipettes out for calibration, every 6 months.
 - b. Calibrate dispenser if used**
 - c. Biomed will perform tachometer check to ensure it is 825+/- 25 RPMs
 - d. Check timer using calibrated NIST timer on line.
- **Dispenser Calibration Check diluent dispenser to ensure delivery volume is +/- 5%
3. ANNUAL
 - a. Have Biomed inspect the cable and wire for damage.

VIII. REFERENCES

Johnson and Johnson, Ortho Clinical Diagnostics, Micro Typing System. Inc. Implementation Guide and Procedures, 5-25-2010
 Ortho MTS Incubator Users Guide 6-30-2004
 Ortho MTS Centrifuge Users Guide Model 5150-60. 10-15-2008
 Ortho MTS Package Inserts, Anti-IgG cards, MTS Diluent 2, Surgiscreen

IX. STAKEHOLDERS

N/A

Policy Title	Cytospin Operating Procedure	Policy #	HEM2407
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 12/2/2020

I. PURPOSE

To provide an easy to read smear from a centrifriged, concentrated fluid sample.

II. POLICY

To assist in obtaining an accurate microscope evaluation.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Label the slide with the patient's LIS number, first and last name and type of fluid. Use the disposable cytofunnel sample chamber with the attached filter card. Place the glass slide in the metal cytoclip, followed by the disposable plastic funnel. Bring the spring clip up and secure under the two retaining hooks. The maximum quantity of supernatant fluid that can be absorbed by a single filter card is 0.5 mL (14 drops using a plastic pipette.) Larger quantities will result in leakage of fluid into the rotor.
2. Clear fluid required 5-10 drops, cloudy fluid required 1-3 drops using a plastic disposable pipette. When the fluid is bloody a 1:5 dilution using saline yields the best smear. When it is grossly bloody, a push pull may be made. Add one drop bovine albumin. Cover the sample chamber with the plastic cap. The Microbiology Department requests a cytospin specimen of cerebral spinal fluid be prepared for them as well. Do not use albumin for the microbiology smear as it can be contaminated. If bacteria are grossly evident on the cytospin preparation, a smear with no albumin should be examined.
3. Replace the inner plastic cover, close the outer lid and spin at 1000 rpm for 6-10 minutes.
4. Remove the sample chamber together with the filter card and slide from the cytospin. The slide should then be lifted clear of the filter card using a "peeling" or "book opening" action to prevent mechanical disturbance of the cell deposit.
5. Air dry smears for 10 minutes, then stain with Wrights-Giemsa (Hema-Tek slide stainer).
6. Cytospin centrifuge is located in the Microbiology department. The hood must be used to open the individual chamber and rack.

V. REFERENCES

Body Fluids, second edition, Carl R. Kjeldsberg, Joseph Knight, American Society of Clinical Pathologist, 1986 pages 158-159
Shandon-Southern Cytospin 2 Operator's Manual, Shandon-Southern Instruments, Inc Sewickley, PA
Shandon package insert, Cytofunnel Disposable sample Chamber, Rev. 1, 1/98 cat. no. 5991040

VI. STAKEHOLDERS

N/A

Policy Title	Roche Cobras U411	Policy #	HEM2507
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 8/18 /2020

I. PURPOSE

The Roche analyzer measures the specific wavelength of each parameter on the Chemstrip 10 UA dipstick. See the package insert for specific chemical principles for each parameter.

II. POLICY

To perform chemical analysis of urine specimens.

III. DEFINITIONS

N/A

IV. PROCEDURE

Materials:

Roche Cobras U411
Roche Chemstrip 10 UA
Urine

Specimen:

A freshly voided urine specimen, first-morning urine specimen or post-prandial urine specimen may be used. Collect the urine specimen in a clean container. A "clean-catch" or catheterized urine specimen is required. Perform testing as soon as possible after collection. Do not centrifuge or add preservatives to the urine specimen prior to performing the dipstick. If testing cannot be performed within one hour after collection, refrigerate the specimen at 2-8 degrees ~~C~~. Bring refrigerated specimens to room temperature before testing. Mix thoroughly before use.

Calibration:

Under routine conditions, the Cobras u 411 should be calibrated every 4 weeks. If the recommended 4 weeks is exceeded, a warning message appears. Calibration must be performed when required.

TO CALIBRATE

Do not touch the elevated areas on the strip. The strip should be used only once.

1. Ensure the analyzer is in standby.
2. Tab to utilities.
3. Touch <tools> icon.
4. Touch <Calibrate> and the check mark.
5. Calibration results will print in approximately one minute.
6. Verify that the printout ~~says~~ "calibration ok".

If calibration is not acceptable, recalibrate with a new calibration strip. If still not resolved, clean the reference pad. If still unsuccessful, call the Roche Hotline. Document on QC log (back side of QC sheet) that you called and the resolution of problem.

Policy Title	Roche Cobras U411	Policy #	HEM2507
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Processing Samples using a Worklist

1. Ensure that the analyzer is in standby.
2. Ensure that the worklist is clear— If not, delete previous accession numbers.
3. Tab to <workplace>.
4. Touch <worklist>.
5. Scan the first barcoded specimen.
6. Briefly dip the test strip into the first sample ensuring that all of the reagent impregnated test areas on the strip are totally immersed, and then rim off excess sample by running the test strip along the edge of the test tube. Do NOT blot on an absorbent paper.
7. Insert the strip into the analyzer.
8. Repeat steps 5-7 for additional specimens.

Quality Control:

Two levels of controls are run each day and with each new lot of Chemstrips— Night shift CLS is responsible for running the daily quality control, but day and evening shift are also responsible for checking and ensuring that it was done. If not, QC should be performed immediately. Quality control material is stored in the serology Isotemp refrigerator in Hematology— Unopened vials are stable until the expiration date on the label. **DATE EACH BOTTLE WHEN IT IS OPENED.** Transfer an aliquot into a 10 x 75-mm centrifuge tube; allow this aliquot to come to room temperature. Immediately recap the original vial and return to the refrigerator.

1. Ensure that the analyzer is in Standby status.
2. Tab to <workplace>.
3. Touch <run control>.
4. Select the control level to be analyzed and touch the check mark.
5. Load the test trip as described under processing samples.
6. Record the results in the quality control binder

The test system is in control when results from both levels of controls are within the expected ranges. Refer to the QC log for values and limits for the Roche Cobras u411 method. If not in control, open a new fresh well-mixed bottle and run at room temperature as a first method to resolve out of control situations. Check the chemstrip, calibrator strip and the control material to ensure they have not expired. Perform maintenance including recalibration— Call the Roche Hot line or the MAS technical assistant hot line for further help.

Roche 1-800-428-2336

MAS 1-800-582-3095

Document any corrective actions on the back of the QC log.

PREVENTATIVE MAINTENANCE

DAILY:

1. Empty the waste tray.
2. Clean test strip transfer system.
3. Check for sufficient paper supply.

LIMITATION OF THE PROCEDURE USING CHEMSTRIP 10 UA

Specific Gravity: The chemical principle of the test may cause slightly different results compared with other specific gravity methods when elevated amounts of certain constituents are present.

Policy Title	Roche Cobras U411	Policy #	HEM2507
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Leukocytes: This test is not affected by erythrocytes in concentrations up to 10,000/uL or by low counts of bacteria common in urine. Do not collect specimens in containers that have been cleaned with strong oxidizing agents (bleach). Urinary glucose excretions >5 g/dL may diminish the intensity of the reaction color. Formaldehyde, gentamicin, imipenem or meropenem may cause false positive reactions. Additionally, possible false positives may occur with cefoxitin, curcumin, levodopa, n-acetyl cysteine, p-aminosalicylic acid or tetracycline. False negative readings might be given during treatment with captopril—High pH values caused by urinary tract infections and a lowered specific gravity might lead to false positive readings in rare cases.

Nitrite: False negative readings may be produced by medications with 2-mercaptoethanesulphonate-sodium (MESNA).

Protein: False positive results may be found during therapy with acetaminophen, chloroquine, levodopa or nitrofurantoin.

Glucose: The effect of ascorbic acid (vitamin C) retained in the urine due to ingestion of vitamin tablets, antibiotics or fruit juices has been eliminated at glucose concentrations of 50 mg/dL and above so that false negative readings rarely occur, even at high concentrations of ascorbic acid (up to 75 mg/dL). False positive readings may be produced by strongly oxidizing cleaning agents or mercetronium etilsulfate in the urine container and medication with 2-mercaptoethanesulphonate-sodium (MESNA). False negative readings may be produced by medications with nitrofurantoin.

Ketones: Red-orange to red color shades, which are readily distinguished from the colors obtained with ketones, can be produced by phthalein compounds that may be administered for liver and kidney function tests. Captopril, curcumin, imipenem and 2-mercaptoethane sulphonate sodium (MESNA) or other sulfhydryl containing compounds may cause false positive results—Formaldehyde may also cause false positive readings.

Urobilinogen: The total absence of urobilinogen cannot be detected. Most urine specimens give a slight pink reaction. This test gives the same color reaction with urobilinogen as with stercobilinogen; however, the differentiation is not of diagnostic importance. Urine from patients treated with p-aminosalicylic acid or sulfamethoxazol may show a false positive reaction. Nitrate concentrations above 0.6 mg/dL or formalin concentrations above 200 mg/dL may cause a decrease in color reaction. Urines with pH values > 9 may show false positive readings.

Bilirubin: Large amounts of ascorbic acid (>40mg/dL) present in the urine following the ingestion of medication containing vitamin C or fruit juices lower the sensitivity of the test. In case of doubt, repeat the test on urine voided at least ten hours after the last administration of vitamin C. Elevated concentrations of nitrite, as in urinary infections, may result in lower bilirubin values. Large amounts of urobilinogen in the urine affect the color change of the bilirubin test. Highly basic urines (pH > 9) might show false positive results—Treatments with 2-mercaptoethanesulphonate-sodium (MESNA) may give false negative results—False positive readings are obtained during treatment with imipenem, penicillin and p-aminosalicylic acid or due to contamination of the urine container with hydrochloric acid.

Blood: False negative readings are obtained when formalin is used to preserve the urine or on medications with nitrofurantoin or quinidines. Nitrite in excess of 0.6 mg/dL in the urine (which is rare in urinary tract infections) do not delay the reaction. Urine from menstruating females occasionally

Policy Title	Roche Cobras U411	Policy #	HEM2507
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yields a positive result. This test has not been found to be affected by the ingestion of reasonable quantities of ascorbic acid (up to 75mg/dL). High counts of leukocytes (500leu/dL), highly basic urines (pH>9) and low specific gravity (<1.005) may show false positive results. Medications with 2-mercaptoethanesulphonatesodium (MESNA) can lead to false positive or false negative reading of reagent pad color changes. Contamination of urine container with hydrochloric acid may result in false positive readings.

V. REFERENCE

Roche Cobras u 411 Analyzer Operator's Manual
Chemstrip 10 UA Package Insert

VI. STAKEHOLDERS

N/A

Policy Title	Fecal Occult Blood	Policy #	HEM2508
Responsible	Laboratory Director	Revised/Reviewed	<u>12/15/2022</u> 09/2020

I. PURPOSE

It is the policy of Watsonville Community Hospital to offer testing of fecal samples for the presence of occult blood.

II. POLICY

To screen for fecal occult blood that can result from colorectal cancer, peptic ulcers, ulcerative colitis, and other conditions.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Storage and Stability

Store Sure-Vue test components at room temperature (15-30deg C.) Do not refrigerate or freeze. Protect from heat and light. Do not use after expiration date and do not use developer from one lot with slides from another lot. Storage conditions and outdates of occult blood test cards will be monitored by the Urinalysis Section Head.

B. Patient Preparation

Certain foods ingested in the 48 hours preceding testing can cause false results.

1. False positive results can be caused by red meats (beef, lamb) and certain raw vegetables, (especially radishes, melons, turnips, and horseradish).
2. Aspirin and non-steroidal anti-inflammatory drugs should be avoided for 48 hours before sample collection, as they can artificially induce bleeding in the gastrointestinal tract.
3. Ascorbic acid (vitamin C) of more than 250mg/day from either tablets or dietary sources can mask the presence of occult blood, causing negative results.

C. Sample Collection

1. Specimens received directly on test cards may be developed immediately.
2. If specimens are submitted in containers, apply a thin smear to the paper in the "A" box of the test slide, using the applicator stick provided. Using the same applicator stick, sample a different part of the stool and apply to the "B" box. Wait 3-5 minutes before developing test.

DO NOT USE TO TEST GASTRIC SPECIMENS

In addition:

1. Fecal samples should not be collected if rectal bleeding, such as hemorrhoids, is present.
2. Pre-menopausal women should not be tested the first 3 days of their menstrual period.
3. For a more complete list of testing recommendations, see manufacturer's instructions.

Policy Title	Fecal Occult Blood	Policy #	HEM2508
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D. Developing the Test

1. Open the flap in the back of the slide and apply 2 drops of Sure-Vue Developer to the paper directly over each smear. Read results within 60 seconds. Any trace of blue color on or at the edge of the smear is positive for occult blood.
2. Some fecal specimens have a high bile content that causes them to appear green. A distinct green color appearing on or at the edge of the sample within 60 seconds after applying the developer should be interpreted as negative for occult blood.

E. RESULTS REPORTING

Results will be recorded in the laboratory computer system.

F. QUALITY CONTROL

1. After developing the test, apply one drop Sure-Vue Developer between the positive and negative Performance Monitor areas. Read results within 60 seconds. If slide and developer are functional, a blue color will appear in the positive Performance Monitor area, while no blue color will appear in the negative Performance Monitor area.
2. Always read the patient test results before developing the Performance Monitor, to avoid the possibility of blue color migrating from the positive area into the sample area, giving a false positive result.
3. If Performance Monitor results are other than expected, disregard patient results and retest using new Hemoccult slide and developer. If still unable to obtain a passing Performance Monitor result, notify the Urinalysis Section Head.
4. Quality control is performed on each new shipment or lot. After a successful QC check, a sticker attesting "QC done" is affixed to the kit.
5. The Urinalysis Section Head or a designee will make monthly inspections of all testing areas to ensure that test cards are stored properly and are not outdated and will perform QC on all open kits.

V. REFERENCES

1. Burtis, Carl and Ashwood, Edward. Tietz Textbook of Clinical Chemistry. WB Sanders, Philadelphia, 1999.
2. Fisher Health Care, A Test for Fecal Occult Blood, package insert, Houston, 1998.

VI. STAKEHOLDERS

N/A

Policy Title	Urinalysis Microscopic	Policy #	HEM2582
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 08/20/2020

I. PURPOSE

A microscopic analysis of urine is an important diagnostic tool for detection of renal and urinary tract disorders.

II. POLICY

To identify cells, casts, bacteria in urine sediment.

III. DEFINITIONS

N/A

IV. PROCEDURE

Materials Required

1. Fisher brand Urisystem conical centrifuge tubes
2. Centrifuge
3. Plastic pipets
4. Fisher brand Urisystem slides
5. Microscope

Centrifuge approximately 12ml urine for 5 minutes at 1500 RPM with a 6-inch rotor. Pour off the supernatant; if confirmatory testing is necessary, save an aliquot. The Fisher brand centrifuge tube automatically saves sufficient urine sediment to perform a microscopic examination. Transfer a drop of re-suspended sediment to a Urisystem slide with coverslip, and examine on low (10X) power. Scan five (5) fields looking for casts and significant crystals. Estimate number of epithelial cells. Then scan five high power (40X) fields looking for RBCs, WBCs, and bacteria. If the sediment is unremarkable (no casts, <3 RBC and <5 WBCs per high power field, no significant crystals or bacteria, and dipstick negative for Nitrite, Leukocyte Esterase, and Blood), then it may be reported as "Microscopic Review Negative". If there are significant findings, then ten fields must be examined and quantitated.

Quality Control, Competency and Proficiency Testing

New testing personnel receive orientation according to a detailed checklist that insures complete initial training. The laboratory is enrolled in a CAP Proficiency Testing program, and receives Kodachrome slides of urine sediments for review 3 times per year. The laboratory has an internal Competency Testing program requiring all testing personnel to examine a urine sediment. Results of this are maintained in the laboratory. The centrifuge has annual preventive maintenance and the speed is checked by the BioMedical Dept.

Results Reporting

All microscopic urine examinations must report values for:

Policy Title	Urinalysis Microscopic	Policy #	HEM2582
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1. WBCs
2. RBCs
3. Epithelial Cells
4. Bacteria
5. Yeast
6. Trichomonas
7. Mucus
8. Casts
9. Crystals

Results are quantitated according to parameters maintained in the laboratory computer database. RBCs, WBCs, and casts are quantitated numerically.

Epithelial cells, crystals, bacteria, yeast, and trichomonas are quantitated as follows:

- 1+ occasional forms noted
- 2+ noted in every field
- 3+ large amounts in every field
- 4+ full field

If these preset parameters are inappropriate, free text reporting may be substituted.

Panic Values

The following findings constitute "Panic Values," and must be called to the attending physician:

1. Positive glucose and ketones (in outpatients only)
2. Urinary Tract Infection in Neonates.

For Criteria, see #VIII below.

These calls must be documented in the urinalysis report.

Submission of Specimens for Culture

The test may be ordered as "Urinalysis Culture if Indicated" (UACIN). The criteria for culture are:

1. Positive Nitrite reaction OR
2. Positive Leukocyte Esterase reaction OR
3. Greater than 10 WBCs per high power field

In addition, there are specific indications for urine culture for children:

1. All children under 1 year* should have a culture (CURN) ordered along with the urinalysis (UA). If this order does not exist, the CLS is to call the physician to obtain one. This order must be documented on the chart, or for outpatients a faxed order obtained and kept in the laboratory.

*** See attached letter from pathologist and micro lead changed to cult to 1 year.**

2. For children older than 1 year but less than 2 years, a UACIN should be ordered. If only a UA is ordered, and a culture is indicated as specified above, the physician must be called. If the culture is declined, this must be documented in the urinalysis report.

Limitations of Procedure

1. Excessive RBCs may obscure other elements in the sediment, and confuse quantitation of WBCs. The RBCs may be lysed using either lyse reagent from the automated cell counter or with acetic acid.

Policy Title	Urinalysis Microscopic	Policy #	HEM2582
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2. Presence of large amounts of crystals may create a similar effect. These can either be dissolved using acid or base, or the sediment may be diluted to obtain a clear view of other elements. The dilution must be taken into account when quantifying the elements observed.

V. REFERENCES

1. Fisherbrand UriSystem package insert, Fisher Scientific, Pittsburgh PA, 1991
2. Graff, Sister Laurine, Handbook of Routine Urinalysis, J P Lippincott Co, Philadelphia, 1983
3. Todd, Sanford, and Davidson, Clinical Diagnosis and Management by Laboratory Methods, W B Saunders, Philadelphia, 1979

VI. STAKEHOLDERS

N/A

Policy Title	Critical Value Reporting	Policy #	HEM131001
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 08/4/2020

I. PURPOSE

To assure quick and accurate reporting of laboratory panic values.

II. POLICY

All critical values are called to the appropriate person.

III. DEFINITIONS

N/A

IV. PROCEDURE

After verifying that an abnormal result is valid the CLS will:

A. Inpatient

1. Immediately call the RN responsible for the patient's care or, if not available, another RN should be notified.
 - a. If there should be any delay in re-running the test for validation the RN should be called to alert him/her of a potential critical value.
2. The RN will repeat the information to ensure accurate communication. The report **MUST** be given to the RN
3. The CLS must use the words "critical value or "panic value" when reporting critical values.
4. The CLS will document the name of the RN taking the information in the Critical Result comment screen in the LIS.
5. The CLS will print the report to the unit.

B. Outpatient:

1. Telephone the physician's office during office hours. Relay the results to the physician or the office nurse.
2. Document the communication in the Critical Result Comment screen in the LIS.
3. Document the attempts made to contact the physician after hours in the Critical result comment screen in the LIS.
4. After two (2) unsuccessful attempts to reach the physician (or the physician on call for the patient), contact the pathologist on call, and he/she will determine what actions to take to ensure the patient receives appropriate medical care.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Delta Check	Policy #	HEM131002
Responsible	Laboratory Director	Revised/Reviewed	10/26/2020 10/26/2022

I. PURPOSE:

Failure of a delta check is caused by one of three possibilities:

- a. The patient's condition and test value did significantly change
- b. There was a specimen misidentification
- c. There was an error in one of the two results used to derive the delta value

Any of these possible causes of a delta check failure may be significant and require immediate intervention by the CLS.

II. POLICY:

If a patient's condition is stable, the results of subsequent testing should also be stable. The differences between consecutive test results, a delta check, should be small. If the delta check is large, the test is considered to have failed a delta check. Whenever a delta check is detected, it must be systematically investigated by the CLS prior to verification of results.

III. DEFINITIONS

N/A

IV. PROCEDURE:

1. All patient testing will be performed as outlined in each section's policy and procedure manuals.
2. Previous results will be checked using the F8, result history, function in the HMS.
3. MCV has an internal delta check value assigned in the HMS. A warning flag will appear in a yellow bar across the bottom of the computer screen. All delta checks require repeat testing to rule out instrument error.
4. The yellow bar requires both an acknowledgement and a comment indicating the rerun value and a reason for the delta check failure. For example, the patient was transfused packed red cells.
5. If an acceptable cause for the failure is not discovered, re-verify the identity of the specimen by checking for agreement between the laboratory label and a nursing label or any hand-written identification on the blood tube.
6. In the case that the delta check is found to be caused by a phlebotomy error, the specimen(s) must be redrawn. Thorough and immediate investigation of phlebotomy errors is required as it may involve more than one patient. Any phlebotomy error must be reported on an incident notification form.
7. Documentation of delta checks will be reviewed by the CLS completing the daily E-signature review of results.

V. REFERENCES

N/A

Policy Title	Delta Check	Policy #	HEM131002
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VI. STAKEHOLDERS

N/A

Policy Title	E-Signature Result Review	Policy #	HEM131003
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 8/18 /2020

I. PURPOSE

To assure appropriate results are reported for each patient.

II. POLICY

Result Review Reports will be evaluated by section heads or designees on a daily basis. Any inconsistencies or results not reported per policy will be investigated and brought to the appropriate technologist's attention for action or correction. A section head or designee may edit, correct, change or amend any result that he or she determines must be corrected on an immediate basis. The reporting technologist will be informed of the section head's action.

III. DEFINITIONS

N/A

IV. PROCEDURE

- A. On a daily basis, Result Review Report will be electronically performed in the HMS by the evening CLS.
- B. To perform a Result Review Report:
 1. From the Laboratory Menu, choose option 17, E-sig Result Review Report.
 2. Enter yesterday's date in the From date/time field and the Thru date/time field. Let the time fields default to *ALL.
 3. Enter LAB in the Department field.
 4. For Sub-department enter "HEM" (See screen shot below), and then repeat the steps below for ~~"HMN"~~ and "COA"

Policy Title	E-Signature Result Review	Policy #	HEM131003
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E-Signature Result Review Report
5/24/10 17:04:07

Type information, press Enter.

From date/time . . . 52010 *ALL weddy hnm
Thru date/time . . . 52010 *ALL weddy hnm
Department . . . LAB F4 for list
Sub-department . . . F4 for list
Procedures . . . F4 for list, blank=all

Order Priority . . . 0=Routine, 1=ASAP, 2=STAT, 3=Timed, 4=Crit., blank=all
Flag . . . C=Critical, A=Abnormal, M=Modified, blank=all
Status . . . C=Canceled, F=Final, P=Preliminary, blank=all
Include Micro . . . Y C=Critical, Y=Yes, N=No

F3=Exit F4=Precept F8=Search

```

5. Result screen appears and review all results using the page down tab.
6. After reviewing the result. Exit by hitting F3 and the E-sig window appears. Answer the following questions;

```

E-Signature Result Review Report

E-signature this report? . . . Y (Y/N)
Is this review complete? . . . Y (Y/N)
Print this report? . . . N (Y/N)
Print exception report? . . . N (Y/N)
All done? . . . Y (Y/N)

F3=Exit F10=Previous

```

C. Evaluate the Result Review Report:

1. Evaluate all critical results for the following criteria:
 - a. All critical results must include a comment that the critical result was called, that the critical result was read back, and who the critical result was called to.
 - b. All modified results must include a comment describing the reason for the modification and, if appropriate, who was notified.
2. Manually entered results must be reviewed by comparing the results from the logbook to the result on the HMS.
3. Each Section Head or designee will investigate items appropriate to his/her section.
4. The following items will be brought to the reporting technologist's attention:
 - a. Critical results lacking any of the information described in C.1.a.
 - b. Modified results lacking a supporting comment.

Policy Title	E-Signature Result Review	Policy #	HEM131003
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c. Any other unusual results requiring explanation.

5. The reporting technologist will review and act on discrepancies, document the resolution, and report the issue to laboratory management.

D. On a daily basis the Section Head or designee will review any final or preliminary microbiology report that was resulted in the previous 24 hours. The chart below lists the action(s) to take when encountering errors on microbiology reports. The review will be documented on the microbiology checklist.

Minor typographic errors

Actions

Misspelling, etc. not effecting proper interpretation of results

Make correction and inform reporting technologist.

Moderate Errors

Actions

Typographical errors causing confusion, omission of canned comments that aid in interpretation of results, failure to finalize final results, failure to add results to preliminary or final reports, improper posting or incomplete reporting of sensitive results.

Make corrections when possible, retrieve erroneous results and print proper results. Confer with technologist making the error.

Major Errors

Action

Entering wrong results, failure to enter results, no documentation available for reliable report, report signed out before due date.

Amend report (leave erroneous results) when possible. Confer with technologist making the error. Call physician when appropriate. Refer to Lab Director or section head.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Proficiency Testing	Policy #	HEM131004
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 08/4 8/2020

1. PURPOSE

The laboratory will perform proficiency testing to assess the accuracy of test results, and to confirm to CLIA regulations.

2. POLICY

Proficiency testing material is supplied through vendors that have been approved through CLIA. The samples are tested in the same manner as patient testing, by a variety of staff members on a rotation basis. Remedial actions and a thorough investigation are taken when results are not within acceptable limits.

3. DEFINITIONS

N/A

4. PROCEDURE

A. Principle:

To comply with federal regulations, testing of proficiency materials will be performed by licensed Clinical Laboratory Scientists in the same manner as patient samples.

B. Specimens

Specimens are mailed to the laboratory on a regular schedule. Section Heads are responsible for contacting the appropriate proficiency-testing agency if specimens have not been received as expected. Specimens should be processed per instructions by the CLS performing the assay.

C. Instruments

Testing must be performed on each instrument routinely used for testing and reporting results. If more than one instrument is used for testing of a specific analyte, the testing can be rotated between instruments.

D. Reagents

Reagents normally used for patient testing will be used for all proficiency testing.

E. Quality Control

- Control materials will be run as they are with patient testing. Extra Quality Control runs are not required for proficiency testing and are inappropriate.

F. Procedure

- PT specimens will be treated as normal patient specimens and processed according to standard operating procedures for that specific analyte.
- PT specimens are usually delivered to the Laboratory Director's office, or a designee, who will then deliver the specimens to the appropriate department.

Policy Title	Proficiency Testing	Policy #	HEM131004
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3. Tests will be entered into the LIS by the Section Head or designee as the survey is received.

G. In the event that the Section Head is not available, the survey will be entered into HMS by the Section Head's bench replacement. Tests will appear on the next worksheet printed and should be done as any other patient appearing on the worksheet. Results shall be entered into the LIS and verified per established protocol.

H. Calculations

Any calculations required for reporting patient results will be calculated by the CLS performing the assay.

I. Reporting Results

1. Clinical Laboratory Scientists performing PT testing will report the results of the test on the survey report form.
2. Clinical Laboratory Scientists performing PT will sign the attestation in the appropriate area of the original report form.
3. Section Heads or designee will be responsible for reviewing the report form for accuracy and completeness.
4. Section Heads or designees are also responsible for informing laboratory management or pathologists of any difficulty in completing PT.
5. For electronic submission, Section Heads or designee will enter the results in the website, print a copy and let a second person review the data entered for accuracy prior to submission.

J. Each Section Head or designee should retain an electronic copy of the entire survey and submit the original to lab management.

K. PT surveys require the medical director or designee's signature prior to mailing. In the event the medical directors are unavailable, lab management is designated as signee on the forms.

L. Evaluation of Results

1. Section Head
 - a. Receives results through the mail.
 - b. Reviews results looking for omissions, unacceptable results, failures, biases, outliers, overall performance and cumulative performance. If unacceptable – Section Head investigates. Testing may be suspended if score is <80% for general testing, < 100% for blood bank.
2. Lab Manager – reviews comments, adds further corrective action, if applicable.
3. Lab Director – performs final review.
 - a. If unsatisfactory, may request additional documentation from SH.
 - b. If satisfactory, signs and returns to Lab Director to be filed.

M. Storage

1. With the exception of whole blood, leftover survey material should be frozen and saved.
2. After PT results have been returned from the accrediting agency, the material may be used for other purposes.

5. REFERENCES

Policy Title	Proficiency Testing	Policy #	HEM131004
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N/A

6. STAKEHOLDERS

N/A

Policy Title	Quality Control	Policy #	HEM131005
Responsible	Laboratory Director	Revised/Reviewed	<u>10/26/2022</u> 08/4 8/2020

I. PURPOSE

To ensure that quality control processes effectively monitor the accuracy and precision of patient results.

II. POLICY

The following procedures will be in effect in order to insure quality lab results.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Each department will establish and maintain quality control logs appropriate to clinical discipline. During orientation and following departmental changes, staff will be in-serviced in departmental QC guidelines, logs and documentation of corrective action.
2. Quality control material will be run and recorded by staff assigned to each department according to the schedule established by the Section Head. Corrective action will be recorded as necessary. Examples of corrective action include:
 - a. Re-run controls
 - b. Re-calibrate analyte
 - c. Replace reagents
 - d. Perform preventative maintenance.
 - e. If all of the above fails, contact the instrument manufacturer technical assistance.
 - f. Perform patient testing on alternative instrument.
3. At the beginning of each workday, the first CLS scheduled in each department will review the previous day's QC and document any errors or omissions. If QC was missed and not performed, immediately perform it when discovered that it was not previously done.
4. Cumulative QC logs are reviewed by each Section Head on a monthly basis. Technical errors will be brought to the CLS's attention by the Section Head.
5. The Laboratory Director and Medical Director will review monthly QC.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Hematology Routine	Policy #	HEM131006
Responsible	Laboratory Director	Revised/Reviewed	8/20/2020 10/26/2022

I. PURPOSE

To assist in the completion of hematology duties.

II. POLICY

To provide a guide for hematology duties that must be followed.

III. PROCEDURE

A. DAILY

1. Print out work lists for hematology under #7 *pending orders worklist for sub dept- HEM-COA-HMAN*. Go back 10 days to include any missing tests. The CLS must resolve any missed test.
~~1.~~
2. File yesterday's slides on shelf - discard last month's slides (if night tech did not).
~~2.~~
3. Check to see that both ~~LH500DxH690T~~ instruments have had latron QC performed and commercial QC performed and mode to mode documented.
- ~~3.~~ ~~4.~~ Check that the daily maintenance for the ~~LH500sDxH690T~~ have been completed, the 45 minute shut down followed by the start up. When the ~~start-up~~start-up is finished, it will automatically print the documentation which includes the back up and running information. File the two pages of ~~start-up~~start-up data (voltages, pressure, as well as back ground and reagent lot information) in the binders in the drawer beneath the appropriate ~~LH500DxH690T~~. *This is usually done by midnight CLS.* This should be followed by the latron primer, latron control, and QC.
~~4.~~
- ~~5.~~ ~~5.~~ Check to see that the hematology QC and coagulation QC has been run for all shifts as appropriate for the previous 24 hours. Check that the QC was in control. Initial that this task was completed on the daily check off list. If QC was not done, rerun the previous shifts QC in addition to your own. E-mail responsible technologist. Also, check that the daily maintenance was recorded for the Stago.
- ~~4.~~ ~~6.~~ All in-patient morning run work should be completed by 0900.
~~6.~~
- ~~7.~~ ~~7.~~ Check that MN shift performed the daily maintenance and QC on the ESR-Auto Plus (run test rack and 2 levels of controls and document). Also, check the sed rate printout and previously reported patient results entered into the HMS computer for accuracy.

Policy Title	Hematology Routine	Policy #	HEM131006
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~~8. 8. Check and initial the non-interfaced QC including recalculating the previously recorded reticulocyte and checking that the result was entered correctly in the HMS. Check and initial the non-interfaced QC checking that the result was entered correctly in the HMS.~~

~~9.~~

~~10.~~

~~11. 9.~~ Perform dayshift qc on both ~~LH500s~~ DxH690Ts and Stago Compact.

**Throughout the shift, complete all patient testing that arrives during the shift.

~~B.~~ ~~B.~~ PMs:

~~1.~~ ~~1.~~ Perform PM qc on both ~~LH500s~~ DxH690Ts and Stago Compact as well as sed rate.

~~2.~~ ~~2.~~ The PM CLS checks the E-Sig result review exception report and initial the check off list after investigating if deltas were documented, if absurd results are valid, and any unexplainable test modification after verifications. All above items should be brought to the attention of the reporting CLS for resolution.

**Throughout the shift, complete all patient testing that arrives during the shift.

~~C.~~

~~C.~~ **NIGHTS:**

~~1.~~ ~~4.~~ At start of shift, check pending lists to check if help is needed anywhere, especially the urine bench.

~~2.~~ ~~2.~~ After midnight, file the previous day's slide box on the shelf and empty the current day's slide box from the previous month and place this empty box on the counter by the scope. Rotate the CBC specimens by throwing away the 48 hour old specimens in the fridge and then placing the current day's specimens in the fridge. Likewise, rotate the coag specimens.

~~3.~~ ~~3.~~ Perform slider stainer maintenance.

~~4.~~ ~~4.~~ At 0300, Perform maintenance on both DxH690Ts. The analyzers are set-up to automatically perform the shutdown and start-up one at a time so there is still an operable analyzer for use for patient testing. DxH690T #1 will shut down at 0100 and DxH690T #2 will shutdown 0205 for 30 mins each. The daily check will automatically print and should be filed in t the binder for the corresponding analyzer. If a reprint is needed, use the calendar icon to access the data and then the print icon. (Chapter 3)

~~At 0300, Perform maintenance on both LH500s: **Do instruments 1 at a time so one is operational and available for patient testing. Click the square, red stop key, change the process type drop down box to shutdown, then click the green arrow key and the instrument will perform the shutdown. After 45 minutes, the LH will automatically do the start-up and print the 2 page daily check report which is to be filed in the binder in the drawer below the the corresponding LH.~~

Policy Title	Hematology Routine	Policy #	HEM131006
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~~If needed, you can force the start-up by stopping the instrument and changing the process type to start-up, and clicking the green arrow. Perform latron primer and latron control by changing process type to Control and type to LTX Prime and then Latex. After, return to auto analysis and CD. Run ABN I (yellow) QC on each instrument in both open and closed mode.~~

~~1. _____~~ 5. Perform urinalysis maintenance as indicated on log and levels 1 & 2 QC.

~~5. _____~~

~~2. _____~~ 6. Perform ESR Plus test rack by pressing and holding red x, then opt 5, insert rack and press ok. It prints almost immediately. Then perform qc on well mixed level 1 & 2 by pressing red x, opt 4 control, opt 1 run, enter level 1 or 2 then press green and place tube. Repeat these steps for the other level.

~~6. _____~~

~~7. _____~~ 7. Stago Record daily instrument temperatures from main menu – status system. Print yesterday's QC control-control, enter on each test, F1 list and F6 print, ESC, F2 other lvl and repeat for all tests, file in binder. Run 0300 QC (PT, PTT, DVT, FIB if ordered) should already be reconstituted and on instrument, post in computer and sign qc log.

~~8. _____~~ 8. At 0500, make pending lists – go back 10 days – HEM HMN COA and sign all check-off lists.

**Throughout the shift, complete all patient testing that arrives during the shift.

D. WEEKLY:

1. Perform maintenance on Wednesday dayshift for both LH500 DxH690T instrument and Stago (See _____ directions under specific instrument).

E. MONTHLY:

1. Print out QC files on both LH500 DxH690T instruments. Copy files to removable drive and submit to Beckman Coulter IQAP program (see white Beckman Coulter Interlaboratory Quality Assurance Program Binder for instructions) File a copy of the results and Levy-Jennings forms in the annual QC binders under the appropriate month. Set up a new QC file in each LH500 DxH690T0-with each new lot. Acceptable ranges are established each month by running QC in parallel with the current lot and calculating our own mean and applying historical SDs.

2. In HMS computer system, print the coag QC for the previous month under 18-QC, 10- for the statistics report and 9-f or the Levey-Jennings. Check to ensure that all 3 shifts ran their QC. If anything is missing, check the daily Stago printout and document it.

D. BIENNIAL:

1. Perform LH500 DxH690T0 calibration.

2. Perform biannual preventative maintenance as appropriate for all instruments or check if done by Biomed or technician.

3. Check for acceptable platelet poor plasma on coagulation centrifuge.

4. Perform Fibrinogen Calibration Verification

5. Perform LH500 DxH690T0 correlations (~~LH1 to LH2, LH1 open to LH1 closed mode, LH2 open to LH2 closed mode~~). (DxH690T #1 to DxH690T #2).

Policy Title	Hematology Routine	Policy #	HEM131006
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- E. ANNUAL:
1. Perform lot to lot correlations on sequestered coagulation reagents.

Policy Title	Hematology Quality Control	Policy #	HEM131007
Responsible	Laboratory Director	Revised/Reviewed	8/18/2020 10/26/2022

I. PURPOSE

To ensure the quality control processes effectively monitor the accuracy and precision of patient result results.

II. POLICY

The following procedures will be in effect in order to ensure quality laboratory results.

III. DEFINITIONS

N/A

IV. PROCEDURE

Each CLS is responsible for:

1. Assessing the quality control results prior to verifying results.
2. If out of control, investigating and documenting action taken.

A. Coulter Cell Counter: ~~LH-500~~ DxH690T

Latron- Night shift will perform a shut down, start up, print out and save the daily checks in a binder which include the background checks, reagents and electronics checks. Nights will also run a latron control to determine if the laser is accurately reading an exact level of latex particles.

Commercial quality control material must be run during each shift.

Controls are run in the "open" primary mode directly into the correct file using the bar code. Controls are run in the secondary "closed" mode using the handheld bar code reader and scanning the predefined bar codes posted on the instrument. (See specific ~~LH-500~~DxH690T-procedure for instructions on actual running of control samples.)

The controls are run in the following schedule in both open and closed modes:

- 0300 (+/- 30 minutes) run ABN I (~~yellow-vial~~)(light lavender)
- 0900 (+/- 30 minutes) run ABN II (~~pink-vial~~)(light purple)
- 1500 (+/- 30 minutes) run NORMAL (~~teal-green-vial~~)(dark purple)
- 2100 (+/- 30 minutes) run ABN I (~~yellow-vial~~)(light lavender)

NEW LOT:

To set-up a new lot of QC material:
Menu>Set-up>QC>New Control from barcode>Scan
Run minimum of 10 times to establish our own mean.
Edit Control>Select mean as target

Policy Title	Hematology Quality Control	Policy #	HEM131007
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~~New files are set up each month by the section head or designee. Select the yellow diamond icon on the command center. Select "quality assurance" and "controls" to display the set up screen. Select the paper icon with the surrounding dots "new control file". Select BCI (for Beckman Coulter), then 5C, and each level. Select the yellow diamond "set up new lot" then follow the instructions on screen. Scan the correct package insert barcode and then select the green check icon. Close the screen with the book icon, and then verify the values scanned correctly. Run a minimum of 10 samples over 5 day's optimum to establish a mean. On each level of QC, hit the mean to lab target button to update the package mean to our established mean.~~

OPEN MODE:—

~~New files are set up each month by the section head or designee. They must be barcoded with a separate barcode. The LH 500 will not accept two files with the same bar code, so the bar code on the tube is reserved for the closed mode files. Post the bar code, using a backing sheet to tape it to the side of the LH 500, same colored post it is recommended. The lot number will be on the barcode. This allows the CLS to barcode the lot number for each level of control in the open mode.~~

~~Alternatively, select the yellow diamond, system set up icon from the command center, followed by the Quality Assurance then the controls icon/folders. Select the yellow page "new control folder" icon, use "other" for the source (NOT BCI it will not work if BCI is chosen). CBC/DIFF is the type and then select and enter each level separately. Select the yellow diamond icon on the right side, to set up new lot, then scan a bar code. Select the green check icon to save.~~

TO SUBMIT DATA TO COULTER FOR ANALYSIS:

At the end of the month, the section head or designee will review the data in each control file. This data has been reviewed daily as well, but the section head or designee will again review before submission to Coulter. All data that has been satisfactory documented as out of control shall be deselected by checking the box on the left side "des". This should be documented as well, as rerun or wrong level or other adequate explanations. Upload the files from the analyzer to IQAP. In a few days, the data will be available for printing from the Beckman Coulter Internet site. Go to qc reports and choose the specific lot number you wish to print. These printouts are kept in a binder for three years.

~~Use a removable hard drive for the instrument computer and insert it into the driver. Open up the QA/QC file, and then select the IQAP icon on the far right side column. Select all three files you wish to submit, save with the green check icon. (You cannot save each lot individually, as the process of downloading from the LH 500 deletes the previous data on the disk, and if you choose one lot, it will be deleted upon choosing the next lot.) Remove the drive when complete and use the desk computer. Go to the Beckman Coulter Internet Site. Choose the correct instrument and follow on-line instructions to "upload qc files." Remove removable drive when finished. In a few days, the data will be available for printing from the Beckman Coulter Internet site. Go to qc reports and choose the specific lot number you wish to print. These printouts are kept in a binder for three years.~~

B. STAGO COMPACT COAGULATION INSTRUMENT:

Two levels of controls, Normal and Abnormal shall be run during each shift at 0300, 0900, 1500, and 2100. QC material shall be reconstituted with DI water and left to sit for 30 minutes before use. Fibrinogen and DDDVT (quantitative d dimer) shall have qc performed only when a test is ordered. Each level of each test of quality control must be printed out by the night shift before the first run of the next day's QC and saved in the daily coagulation QC binder. This is to ensure that we have an alternate method of saving QC.

Policy Title	Hematology Quality Control	Policy #	HEM131007
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~~C. SEROLOGICAL DDIMER/ DDDIC TESTING:~~

~~Two levels of controls, positive and negative are included in each run of testing. Control solutions must be tested by the same procedures as patient samples. The reaction between the positive control and the reagent should show a clear agglutination, different from the uniform appearance of the negative control. If no agglutination takes place, the test should be repeated and the kit discarded if repeatedly nonreactive.~~

D.C. Sedimentation Rate:

Two levels of control are run each 8 hour shift of use. If results are unacceptable, a new working tube should be set up from the bottle after it is thoroughly mixed. Streck recommends vortexing bottle to ensure proper mixing. In addition a rack test is performed each morning as an internal quality control.

V. REFERENCES:

Beckman Coulter LH500 instrument manuals 2004 and 1999.

Streck ESR-check package insert and ESR-Vacuum tubes package insert.

VI. STAKEHOLDERS

N/A

Policy Title	Hematek Slide Stainer	Policy #	HEM131008
Responsible	Laboratory Director	Revised/Reviewed	8/18/2020 10/26/2022

I. PURPOSE:

A Wright-Giemsa stain is used for the automated slide stainer. The Wright-Giemsa stain provides a more intense coloration of platelets and neutrophils. In the Romanowsky modified method of the Wright-Giemsa stain, the acidic aniline dye-eosin unites with the basic elements of the cell such as the cytoplasm and hemoglobin, while the basic aniline dye-methylene blue combines with the acidic elements such as nucleic acid, the nucleoproteins of the nuclei.

II. POLICY:

To stain blood films in order to perform a manual blood cell differential and evaluation.

III. PROCEDURE:

Specimen:

Fresh EDTA blood should be used to prepare smears. For optimal results, blood less than four hours old should be used. Nuclear disintegration, as well as other morphological changes may occur if the smear making is delayed. Heparin or oxalate should not be used as an anticoagulant due to undesirable morphological reactions. This laboratory will use only uncoagulated whole blood or EDTA blood to make blood smears. The smear should be labeled with the patient's full name, and the laboratory accession number.

Reagents and ~~Supplies~~Supplies:

Fisher ~~Scientific~~WrightScientific Wright-Giemsa stain pack

The Hematek stain pack contains Wright-Giemsa stain in three separate bottles, including the stain, the buffer and the rinse. The stain contains Wright Stain in methanol and it may be fatal or cause blindness if swallowed. It is flammable and has harmful vapors.

The buffer contains a phosphate buffer with a wetting agent and preservative. The rinse also contains a phosphate buffer with wetting agent and contains harmful vapors.

The stain is kept in its original sealed container (no harmful vapors) below the stainer. It should be stored at room temperature and not refrigerated. Methanol is kept in one-gallon containers in the flammable safety storage cabinet in microbiology. A pre-labeled, 500-ml plastic bottle is kept in Hematology. Slides are on a standing order and are kept in the storeroom. Stainer cannulas and tubing are kept in the drawer.

Stain Acceptability:

The following is a list of expected results:

<u>Nucleus</u>	<u>granules</u>	<u>cytoplasm</u>	
Erythrocytes	--	--	pink
Leukocytes			
Granulocytes			
PMNS	purple	red-lilac	light pink

Policy Title	Hematek Slide Stainer	Policy #	HEM131008
---------------------	-----------------------	-----------------	-----------

Eosinophils	blue	red orange	light pink
Basophils	dark blue	dark purple	light pink
Monocytes	violet	--	light blue
Lymphocytes	violet	--	blue
Platelets	--	purple	lilac

If the above-expected results are not achieved, maintenance may be necessary. A new smear should be made and appropriate maintenance should be done. The NEATSTAIN (above the microscope) should be used if expected results cannot be obtained or if the stainer is not operational.

Blood Film Preparation:

1. Using a frosted edge microscope slide, make a push, peripheral blood smear. A Diff-Safe device may be used to obtain the drop of blood. The Diff-Safe should only be used one time. *Do not use Diff-safe on tubes which have been opened and re-closed as blood may rapidly pour out from such specimens*
2. Only the center two inches of this 3-inch slide will be stained. The feather edge must fall within 1/2 inch of either side.
3. Slides without a feather edge, will have a disproportionate differential, and must be remade.
4. Allow the smear to air dry completely. Write the patient's full name and laboratory ~~accession~~accession number on the frosted end with a pencil.

Hematek Stainer:

1. Place blood smear in corresponding grooves in the slide leading area on the right side of the Hematek. Slides should fit precisely into the holding grooves. MISALIGNED SLIDES WILL BREAK.
2. The blood smear side should face left and will be stained by direct contact with the platen.
3. Always prime an unbroken run of slides with a blank slide. If it has been several hours since use, prime with several blank slides.
4. Staining time is approximately 9 1/2 minutes for the first slide to process completely.

Neat Stain Manual Back-Up Method:

1. The stain kit is a ~~self-contained~~self-contained Wright stain which can produce slides in less than 30 seconds.
2. It is located in the reagent cabinet above the microscope.
3. Air-dried smears should be dipped 5 times (one second each dip) in each container (fixative, solution I and solution II).
4. The foil container may be reattached and stain kept for one week.
5. Allow smear to air dry upon completion.

Buffy Coat Preparations:

—Specimens with leukopenia may require a buffy coat to harvest sufficient cells for a manual differential. *Red cell morphology and platelet estimates must be made from the original (non-buffy) smear.*

1. Seditube tubes may be used to spin approximately one ml of well-mixed blood. A long pipette must be used to load the Seditube. Seditubes and long pipettes are above the pipette shelf.
2. Place the Seditube inside an empty 10 ml red vacutainer tube which has had the stopper removed.
3. Spin the Seditube in the chemistry centrifuge, making sure it has sufficient clearance to spin.
4. Using the same long glass pipette, remove the buffy coat from the spun Seditube.

Policy Title	Hematek Slide Stainer	Policy #	HEM131008
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- Using a wooden applicator stick, mix the buffy coat before making the push smear, air dry and proceed as above.

Maintenance: (performed on night shift)

Daily:

- If opening a new stain pack, record the date opened and clean cannula #1. To do this, remove all of the cannulas from their corresponding stain bottles, place cannula #1 into a tube of methanol and prime the stainer until all methanol is aspirated from the tube. Reinsert all the cannulas into their corresponding stain bottles and prime the stain until it is visible in the tubing with no air bubbles.
- Empty the liquid waste located in the center front of the instrument.
- Flood platen with methanol and using a soft gauze, wipe the platen clean. *Wipe from right to left.*
- Prime until all three reagents are flowing through their respective orifices, and wipe from right to left.
- Run 4-5 blank slides ahead of the first slide to be stained.
- Initial the maintenance chart in the daily hematology checklist binder.

Weekly: Run methanol thru cannula number one by removing all the cannulas from the stain pack, then fill a small, empty tube with methanol and place only cannula number one into tube, then press the prime button until all this methanol aspirates thru the cannula and empties completely out of the tubing line while wiping the platen from right to left. Replace all of the cannulas back into their appropriate stain receptacles, and prime the stain until the lines are full.

Every six months:

- Replace the underplaten tubing.
 - Replace tubing and cannulas as needed.
- See Hematek operation manual for further details.

Limitations:

Staining problems/Troubleshooting

- Excessive blue stain: thick films, prolonged staining time, inadequate washing, stain or diluent too alkaline or clogged manifold.
- Excessive pink stain: Insufficient staining, prolonged wash time, or too high acidity of the stain or buffer.
- Precipitate on the film may be due to unclean slides, drying during the period of staining or inadequate washing of the slide at the end of the staining period.
- Uneven staining: Mixing grooves on the platen are dirty; slides are warped.
- Pale staining: Improper stain-to-buffer ratio, stain volume too high, (increasing stain may decrease stain intensity) outdated stain pack. See operation manual for actions.

IV. REFERENCES:

Todd, Sanford, and Davidson, "Clinical Diagnosis and Management by Laboratory Methods"
Hematek Operating Manual, 1990, Miles, Inc., Diagnostics Division, Elkhart, IN 46515 USA
Raphael, Lynch's Medical Laboratory Technology
Fisher Scientific Stain product insert
Astral Diagnostics Neat Stain product insert

Policy Title	Hematek Slide Stainer	Policy #	HEM131008
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Policy Title	Malaria Smears	Policy #	HEM131010
Responsible	Laboratory Director	Revised/Reviewed	08/20/2020 10/26/2022

I. PURPOSE

Thick and thin blood smears are utilized for the detection and identification of malaria. Thick films are preferred for detecting malaria infections. This permits one to examine volumes of blood approximately ten-fold greater than on thin smears.

II. POLICY

To assist in detecting blood parasites.

III. DEFINITIONS

N/A

IV. PROCEDURE

SPECIMEN:

Blood for examination may be obtained by finger stick or venipuncture. Blood smears, especially for diagnosis of malaria should not be prepared from clotted blood. Ensure that the time that the specimen was drawn is notated as this will allow correlation between the results of the blood smear and the patient's symptoms (e.g. fever patterns).

REAGENTS AND SUPPLIES:

1. Alcohol cleaned supplies
2. Applicator sticks
3. Coplin jars (2)
4. ENG Scientific, Inc. Malaria Quick Stain Kit - For Thick Smears
(Located on shelf above the second microscope).
 - a. Solution 1 - Methylene Blue and Giemsa
 - b. Solution 2 - Eosin
5. Ames Hema-Tek 2000 stainer with Wrights-Giemsa Stain -for thin smear

THIN SMEARS:

1. Clean slides with alcohol
2. Prepare several thin smears as you would smears for CBC and stain in Hema-Tek stainer with Wrights-Giemsa Stain.

THICK SMEARS:

1. Clean slides with alcohol.
2. Place 1 - 2 drops of blood on slide. Spread the blood on the smear with an applicator stick in a circular motion about 1 - 1.5 cm in diameter (approximately the size of a nickel). The center of the smear should be thicker than the outer edge. The density of the smear should be such that fine print can just be read through the center portion when wet. Make 4 thick smears.

Policy Title	Malaria Smears	Policy #	HEM131010
---------------------	----------------	-----------------	-----------

3. Allow the slides to dry overnight (or at least 8 hours) in horizontal position. Avoid heat. Heat interferes with dehemoglobinization.
4. Fill one coplin jar with Solution 1 and the other coplin jar with Solution 2.
5. Place 1 smear in Solution 1 for 3 seconds.
6. Remove and rinse under tap water until all stain is removed.
7. Remove excess water and place in Solution 2 for 5 seconds.
8. Rinse under tap water, air dry, and check it under oil immersion lens.
9. If the smear is stained too light or too dark adjust staining time slightly on the remaining 3 smears.
10. The thin slide should be examined with the oil immersion lens and reported by the CLS.
11. The thick slide is submitted to the pathologist to read.

INTERPRETATION OF RESULTS:

Ring forms of malaria will often have the appearance of punctuation marks rather than complete rings, and the presence of red chromatin and blue cytoplasm should be required to identify them as parasites.

V. RESULTS

Report the thin slide result as negative or positive. If positive, use F6 comment to state Plasmodium or any other parasite seen. We only screen and do not differentiate the specific specie type. Result with F9 in order for it to remain on the pending list until the pathologist's report is received. Once received, the result may be "final" reported using F10.

VI. REFERENCES

Todd, Sanford, and Davidson. "Clinical Diagnosis and Management by Laboratory Methods," 17th edition, pp 1211, 1218-1227.
Product insert from ENG Inc. Scientific Malarial Quick Stain Kit.

Policy Title	Manual Body Fluid Counts	Policy #	HEM131011
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/26/2022

I. PURPOSE

Body fluids: CSF, Pleural (thoracentesis, chest fluid), Synovial (joint fluid), Peritoneal (ascites, paracentesis fluid), and pericardial all may have cell counts and cell differentials to help diagnose or rule out infection, malignancy, injury or other pathology.

II. POLICY

To provide the clinician with qualitative and quantitative results as to cellular content

III. PROCEDURE

1. The fluid should be well mixed. It must be properly labeled, not received with a needle attached, and not clotted.
2. If the specimen is obviously bloody or if the cells are too numerous to count, the specimen should be diluted with saline—Make the lowest dilution possible that will allow the cells to be distributed as a monolayer and easily counted. For example, using a 100 microliter pipette dilute 100 microliters of sample with 100 microliters of saline and carefully mix. The resultant count must be multiplied by two. A larger dilution may be used if necessary but is also dependent on the total amount of specimen available.
3. Fill a disposable C-Chip hemocytometer using a 10 microliter pipette.
4. Allow the cells to sit undisturbed for 10 minutes in a covered petri dish with a moistened filter paper beneath—If a synovial fluid specimen is highly viscous, it may need to stand for more than 30 minutes before the cells can settle and can be counted.
5. The number of cells present determines the area to be counted. The area of the entire chamber is 9 mm²

CALCULATIONS:

$$\text{TOTAL CELLS /}\mu\text{L} = \frac{\# \text{ cells counted} \times \text{dilution}}{\# \text{ squares} \times \text{volume of each square}}$$

1. If more than 200 cells are present in each square millimeter of the chamber, count the cells in the 5 small squares (RBC area) in the center square (A,B,C,D,E)

$$\frac{\# \text{ cells} \times \text{dilution}}{5 \times .004} = \text{cells counted} / \mu\text{L}$$

(or cells x 50 x dilution)

2. If more than 200 cells are present in all 9 square millimeters of the chamber.

Count the cells in each of the four corners (WBC areas)

Policy Title	Manual Body Fluid Counts	Policy #	HEM131011
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(1,2,3,4)

#cells x dilution =

4 x 0.1

(or cells x 2.5 x dilution)

3. If fewer than 200 cells are present in the entire chamber, count all the cells in all 9 squares

cells x dilution

9 x 0.1

(or cells x 1.1 x dilution)

CELLULAR APPEARANCE:

Perform a differential if WBCs are greater than 5 cells/uL.

RBCs have distinct outlines with halos and clear centers. If crenated, they may have fine-pointed projections.

WBCs appear granular; these include polys, lymphocytes, monocytes (aka macrophages).

**Differences of counts between the two sides of the hemacytometer OF OVER 10% indicates poor distribution which requires the procedure to be repeated.

Mesothelial cells and malignant cells may be difficult to distinguish. Pathology Review is required for all suspicious cells. If cells appear to have a high nuclear to cytoplasmic ratio, increased cell and nuclear size, irregularly shaped nuclei, atypical nuclear chromatin pattern, or are clustering, comment "Sent for Pathologist Review" and submit to pathology.

Mesothelial cells are lining cells of pleural, pericardial and peritoneal cavities. (They are NOT seen in CSF). Mesothelial cells are large, their nuclear to cytoplasmic ratio is low, the nucleus is often eccentrically placed, and the cytoplasm is light to dark blue. Mesothelial cells may proliferate in chronic effusions. They may have multiple nuclei (but these nuclei will be of equal size and have a smooth nuclear membrane.) Mesothelial cells may also be found in clusters.

Tissue cells are usually large granular cells with irregular outlines. Broken cells or tissue cells should not be included in the total count.

~~Choroid~~Choroid plexus cells may be seen in normal CSF.

For synovial fluids, neutrophils may contain vacuoles, fat droplets, bacteria or crystals. It is common for the nuclei to be pyknotic. A high percentage of PMNS (greater than 80%) is highly suggestive of septic arthritis. The monocytes and macrophages may be similar to blood monocytes, but often show a variable morphologic structure and may be difficult to distinguish from synovial lining cells. These latter cells also resemble mesothelial cells. The presence of synovial lining cells does not appear to have any specific diagnostic significance.

Any malignant appearing or blast seen in CSF or other body fluids must be sent for a Pathologist Review.

Policy Title	Manual Body Fluid Counts	Policy #	HEM131011
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For additional information, refer to pages 227-255 in CAP Color Atlas of Body Fluids, Galagan, Blomberg, Cornbleet and Glassy MDs, 2006.

Calculations

$$\text{Total cells counted/ uL} = \frac{\# \text{ cells} \times \text{dilution}}{\# \text{ squares} \times \text{volume each}}$$

$$\text{Volume of WBC square} = 0.1 \text{ uL}$$

$$\text{Volume of RBC square} = 0.004 \text{ uL}$$

6. Verify the manual count by comparing to a cytospin stained smear. Perform the white cell differential from the stained smear.

7. **TURBIDITY:**

CSF is normally clear, transudates are clear, exudates are cloudy. (Body fluids from pleural, pericardial or peritoneal cavities can be either transudates or exudates. Transudates are fluids that have gathered due to systemic disease; CHF for example. Exudates are due to localized problems such as inflammation, malignancy or infection.) Turbidity can be caused by leukocytes, erythrocytes, microorganisms or protein. ~~—~~ Turbidity is determined upon the **uncentrifuged specimen** as follows:

1+ = slightly cloudy

2+= turbid, but can read newsprint through tube

3+= cannot easily read newsprint through tube

4+= cannot read newsprint through tube

8. **COLOR:**

The color of the supernatant of centrifuged specimen should be reported as clear, xanthochromic, red, or straw. In traumatic samples, the supernatant typically is crystal clear, while in subarachnoid hemorrhage, the supernatant usually is xanthochromic.

****REMEMBER** Turbidity is assessed on uncentrifuged sample, whereas color is assessed on the supernatant of the centrifuged sample.**

9. **QUALITY CONTROL:**

STRECK Cell-Chex must be counted once every 8 hours when a manual cell count is performed. ~~—~~ In addition, duplicate counting of each side of the hemocytometer must agree within 10% provided that there are ≥ 20 cells present. If not, the procedure must be repeated. ~~—~~ A stained smear should be made to verify that cells are present.

10. **RESULTS:**

All body fluid cell counts may be ordered STAT with an expected turnaround time of one hour. Blasts or malignant cells seen in body fluids are considered to be Critical Values and must be reported to a nurse or physician.

Policy Title	Manual Body Fluid Counts	Policy #	HEM131011
---------------------	--------------------------	-----------------	-----------

There are five choices for "SOUBF" or source of body fluid:

1. CSF
2. pleural (thoracentesis, chest fluid)
3. synovial (joint)
4. peritoneal (ascites, paracentesis)
5. pericardial

Red and white cell counts are reported as cells/microliter. The differential may include %polys, % lymphs, % monos, % eos, % mesothel. (Mesothelial cells is not an option if the body fluid is CSF.) If other cells are noted, for example nucleated blood cells in a bloody CSF tap, or suspicious for blasts in CSF, add cells as a comment.

CSF NORMAL RANGES:

	Neonates	adults
Total white count	0-30/uL	0-5/uL
Neutrophils	0-8%	0-6%
Lymphocytes	5-35%	40-80%
Monocytes	50-90%	15-45%

Synovial Fluid Ranges:

Leukocyte count	0 - 150/uL
Neutrophils	< 25%
Mononuclear phagocytes (monocytes and histiocytes)	<70%
Lymphs	<75%

IV. REFERENCES:

Kjeldsberg and Knight, BODY FLUIDS, third edition, 1993, Chapers 2,3,4,6, Appendix A (pages 316-320).

Todd, Sanford and Davidson CLINICAL DIAGNOSIS AND MANAGEMENT BY LABORATORY METHODS, 1979 , Chapter 18, page 638.

Galagan,Blomberg, Cornbleet and Glassy COLOR ATLAS OF BODY FLUIDS, CAP 2006

Policy Title	Pathologist's Review of Hematology Smears	Policy #	HEM131012
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/26/2022

I. PURPOSE

The purpose of the pathologist review is to avoid missing a hematological malignancy, to help identify a life threatening medical condition such as DIC (disseminated intravascular coagulation) or TTP (thrombotic thrombocytopenia purpura) or to educate the CLS who has questions about a smear.

II. POLICY

A pathologist should review stained blood smears when the following are encountered for the first time. On weekends and holidays, it is up to the discretion of the CLS to contact the pathologist on call if the CLS believes that a delay of review could affect patient care (*indicates categories which may be significant.)

III. PROCEDURE

*BLASTS - *except on patients known to have blasts (by previous review)*- bring to the attention of the Pathologist by bringing to pathology office as soon as possible, or it after hours, leave out on counter with a note for the next day staff to bring to the pathologist as soon as possible (next day shift).

*MONOCYTES - >20% and WBC is above upper limit of reference range.

*PLATELETS - submit to pathologist if less than 50,000 only if combined with schistocytes or spherocytes.

*ORGANISMS -Malaria, Borrelia, fungi or suspicious for Ehrlichiosis (intraleukocytic inclusion bodies) or any other organisms or suspected organism

*MYELOCYTES OR PROMYELOCYTES -(except known acute infection or known oncology patients)

*QUESTIONABLE CELLS

*CELLS SUSPICIOUS FOR MALIGNANCY FROM BODY FLUIDS –fluids with clusters of cells- any questionable cells or cells suspicious of malignancy

PELGER HUET ANOMALY

EOSINOPHILIA – greater than 50% eosinophilia

NUCLEATED RED BLOOD CELLS –(except on infants less than 2 weeks old or oncology patients if greater than 5 per 100 WBCs)

SIGNIFICANT ROULEAUX

Policy Title	Pathologist's Review of Hematology Smears	Policy #	HEM131012
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LYMPHOCYTES - absolute greater than ~~4.0~~5.0 on adults (except children less than 13 years)

ATYPICAL LYMPHOCYTES - >10%

IV. ENTERING PS RESULTS

- In HMS, check the HEM pending list using "7 Pending Orders"
(with a minimum back date of 10 days)
- Locate the accession # of the PS result that is to be entered
- Using "3 Work With Orders," enter the desired accession #, and enter for text lines

- In Mailgate (after opening thru WCH Outlook email), open the secure email with the patient's name of the path review that is being entered.
- Verify that the name, MR#, and date of birth match in both the HMS and the path review document.
- Highlight the text in the path review and copy it, and then use edit in HMS (top, left) to paste it into the results. If the entire path review does not fit, this process will need to be repeated for the remaining text with page down in HMS for more space. Ensure that the address of Dominican Pathology is also included in the HMS result.

- Slides can then be filed in the PS slide box and copies of the reports may be filed in the PS binders.

Policy Title	Pelger-Huet Anomaly on Manual WBC Differentials	Policy #	HEM131013
Responsible	Laboratory Director	Revised/Reviewed	08/18/2020 10/26/2022

I. PURPOSE

The Pelger-Huet anomaly is an autosomal dominant condition involving the failure of normal segmentation of granulocytic nuclei. Most nuclei are band shaped to have two segments but no more. The classic Pelger-Huet nucleus has a “pince-nez” conformation, which resembles eyeglasses or dumb bells with two symmetric lobes being joined by a filament. The chromatin is quite coarse, and these are not normal young band forms. When a large number of band neutrophils appear in the differential count in a patient without infection or other cause, a careful analysis of the blood films of the patient and of family members will occasionally establish the presence of the Pelger-Huet anomaly. In a heterozygote, the nucleus has a characteristic bilobed appearance. Monolobated cells are also found. The homozygous state is extremely rare, with most neutrophils appearing monolobated. The cells are functionally normal.

II. POLICY

To assist in determining an accurate white blood cell differential.

III. DEFINITIONS

N/A

IV. PROCEDURE

While doing a white blood cell differential, if Pelger-Huet anomaly is suspected, count all the segmented, band neutrophils and any monolobed neutrophils as one cell type. Do not differentiate them. This condition is observed in 1 out of 6000 individuals. Report as ____% segs/bands (Pelger-Huet anomaly) under the % segs category. Next to the WBC count, add the following free text remarks:

“Possible Pelger-Huet anomaly, ____% Pelger-Huet neutrophils (segmented cells and “bands”). Submit the smear to the pathologist for review.”

LIMITATIONS:

Limitations are the same as for doing typical wbc manual differentials. Care must be taken to distinguish Pelger-Huet cells from typical left shift due to infections. Metamyelocytes and bands are seen in infections. A similar appearing acquired disorder of nuclear segmentation in granulocytes may occasionally be found in cases of myeloproliferative disorders, myelodysplastic disorders, some infections and after exposure to certain drugs. This is sometimes called the pseudo-Pelger-Huet anomaly (but these cells are classified as bands). In addition to the band forms and neutrophils with only two segments, mature cells with round, nonsegmented nuclei and coarse chromatin are common, in contrast to the congenital Pelger-Huet anomaly, ring-shaped (donut) and other abnormal nuclei may be seen and the cytoplasm is usually hypogranular in the pseudo-Pelger Huet condition.

V. REFERENCES

Henry, “Clinical Diagnosis and Management by Laboratory Methods,” Kjeldsberg, Hematologic Disorder

VI. STAKEHOLDERS

N/A

Policy Title	Polar Biffringence for Crystals	Policy #	HEM131014
Responsible	Laboratory Director	Revised/Reviewed	08/20/2020 10/26/2022

I. PURPOSE

To provide directions for the use of the polarizing lens to aid in identifying any crystals found in body fluids; e.g., synovial fluid. A polarizing microscope contains two polarizing lenses and a quartz compensator. One polarizer is situated below the condenser, and the second polarizing lens is located above the objective (the analyzer). A first-order red compensator is placed between the polarize and the analyzer; this retards the polarized light so that the field background becomes red instead of black and separates the light into components of slow and fast vibration.

II. POLICY

To examine specimens that may contain crystals.

III. DEFINITIONS

N/A

IV. PROCEDURE

EQUIPMENT & SUPPLIES:

Microscope, with red compensator (Olympus in Hematology)

Polarizing lens - located in container labeled "polar birefringens" on shelf above microscope in hematology.

PROCEDURE:

1. Prepare cover-slipped slide of fluid to be examined.
2. Remove blue glass filter from over the light source (beneath the condenser). It lifts out.
3. Place round polarizing lens (found in polar birefringens kit) over the light source in place of the blue filter. This lens rotates by finger manipulation to obtain polarized light.
4. Loosen the screw for the upper polarizing plate above the objective turret.
5. Gently push the polarizing lens to the left. Now rotate the lower polarizing lens to obtain a black background.
6. The smaller slider labeled with "530 nm" (the red compensator) should now be pushed to the left to obtain the red filter background.
7. Using this set-up, the flow component of the compensator is North-South on the microscope field. You will be looking "north" and your left hand will be "west"--your right hand is "east," and you are "south" of the microscope.

Uric acid crystals, also known as monosodium urate (MSU), will appear YELLOW on the N-S axis and BLUE on the E-W axis. Calcium pyrophosphate dihydrate (CPPD) crystals are exactly the opposite: they appear BLUE on the N-S axis, and YELLOW on the E-W axis.

8. Search the slide for birefringent material. If crystals are observed, note whether they are intracellular or extracellular. (Crystals within WBC's are more significant).

Policy Title	Polar Bifringence for Crystals	Policy #	HEM131014
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9. If crystals are present, center one under the 10X objective. Now loosen the knurled knob facing you, just below the edge of the stage. You can now rotate the stage slowly to see the crystal change from blue to yellow or yellow to blue. Rotate slowly on a lower power to get the feel for this.
10. When you have completed examining the wet prep or slide, please return the microscope to the state in which you found it. Remove the lower polarizing lens and pull out the upper polarizing lens. Tighten the knobs at polarizer slider and stage levels. Replace blue glass filter over light source.
11. Clean the microscope stage, if needed, after removing specimen.

QUALITY CONTROL:

Use the pre made slide labeled "uric acid" found in the polar birefringence kit to confirm the polarizing microscope is properly set up. The positive control slide must be used each time crystals are observed. Use the log in the "Non-interfaced Log" binder to document the results from the known positive slide, and to document results from the patient. Indicate whether the crystals, if seen, are intracellular, extracellular or both, as well as if crystals are present and of what type.

INTERPRETATION OF RESULTS:

1. URIC ACID: Crystals are yellow when their long axis is parallel to the slow component of the compensator (when their long axis is running "North-South" with our set-up); blue when perpendicular. MSU crystals are strongly birefringent: they appear bright against a dark, fully polarized background, and are called 'negatively' birefringent.
2. CALCIUM PYROPHOSPHATE: Crystals are blue when parallel, (N-S); yellow when perpendicular (E-W). CPPD crystals are rod-like, plate-like, or rhomboid. The crystals are weakly birefringent - they are pale against the dark background of polarized light, and are called 'positively' birefringent.
3. CHOLESTEROL: Crystals usually have the appearance of rectangular, notched plates, but occasionally may appear as long, birefringent needles or rhomboids.
4. CALCIUM OXALATE: "Envelope" shaped crystals which look like small squares crossed by intersecting diagonal lines.

REPORTING OF RESULTS:

In the HMS computer, results are entered in the field "POLB." Use the "F4" look-up key to choose the result options. A comment may be added with "F6" to annotate if crystals are intra or extra-cellular, or both.

V. REFERENCES

Todd, Sanford, and Davidson, Clinical Diagnosis and Management By Laboratory Methods

VI. STAKEHOLDERS

N/A

Policy Title	Sedimentation Rate (Streck- ESR Auto Plus)	Policy #	HEM131016
Responsible	Laboratory Director	Revised/Reviewed	020 10/26/2022

I. PURPOSE

The Erythrocyte Sedimentation Rate (ESR) measures the settling of erythrocytes in diluted human ESR- Auto Plus measures the millimeters (mm) per hour.

II. POLICY

To obtain valid Erythrocyte Sedimentation Rate.

III. DEFINITIONS

N/A

IV. PROCEDURE

MATERIALS:

1. Streck ESR-Auto Plus automated erythrocyte sedimentation rate reader.
2. 1.2ml ESR-Vacuum tubes
3. Disposable pipettes

SPECIMEN:

1. EDTA specimen or citrated plasma drawn directly into the ESR-vacuum tube.
2. The specimen is good for 4 hours at room temperature or 72 hours at 2-8 degrees Celsius centigrade. Blood must be brought to room temperature before testing.
3. Specimen must be mixed well. If it is drawn directly into the ESR-vacuum tube, a minimum of 6 complete rotations is required. The air bubble in the tube must reach the opposite end between every inversion. If the specimen is to be transferred from an edta tube into the ESR-vacuum tube, the same procedure is to be followed to insure proper mixing. If the citrate is not properly mixed with the blood, microscopic clots may form and cause results to appear higher than they actually are.

PROCEDURE:

1. If specimen was drawn directly into the ESR-vacuum tube, proceed to step 3.
2. If specimen was drawn into a purple edta tube, remove well mixed aliquot of whole blood (1.2 ml) via a plastic pipette and put into the ESR-vacuum tube (fill to the black line within 5 mm)
3. Thorough mixing is very important! Mix the ESR-vacuum tube a minimum of 6 times, watching the air bubble in the tube reach the opposite end between each inversion. Holding the tube at an angle of 35 degrees will facilitate the mixing process.
4. Immediately after mixing, check that the instrument is ready to accept new samples (if it is in standby mode and displays the time followed by "NEXT SAMPLE--")
5. Scan the barcode or manually enter the 5 digit accession number. Use the "NOT OK" key to delete any incorrect digits, and the "OK" key to confirm when ready.

Policy Title	Sedimentation Rate (Streck- ESR Auto Plus)	Policy #	HEM131016
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6. When prompted (display will read "insert {LIS number chosen} in a free position") then insert the new well-mixed, room temperature sample into any free position indicated by a green light. The position will then turn red and the ESR Auto Plus will start testing.
7. The instrument will automatically read and print the result when it is completed. It is very important that the sample be at room temperature and is properly mixed before analyzing. A well-settled specimen may require several minutes of mixing on the mechanical mixer.
8. In 30 minutes, the instrument will automatically read and print the result.

NORMAL VALUES:

Male age <50 year 0-15
age >= 50 years 0-20

Female age <50 years 0-20
age >= 50 years 0-30

INTERPRETATION OF RESULTS:

Factors which accelerate ESR:

1. Elevated levels of fibrinogen.
2. Elevated levels of globulin.
3. Cholesterol
4. Anemia
5. Macrocytes

Factors which retard ESR:

1. Albumin
2. Lecithin
3. Microcytes
4. Irregularly shaped RBC's, for example spherocytes, sickle cells.

The ESR is higher in women than in men. In pregnancy, the ESR increases moderately, beginning in the tenth to twelfth week. Normal rates return about one month post partum. The ESR tends to be markedly elevated in monoclonal blood protein disorders such as multiple myeloma or macroglobulinemia, in severe polyclonal hyperglobulinemia due to inflammatory disease and in hyperfibrinogenemia's. Moderate elevations are common in active inflammatory disease such as rheumatoid arthritis, chronic infections, collagen disease, and in neoplastic disease.

QUALITY CONTROL:

Two levels of controls are to be run each 8 hour shift if a patient test is ordered. In addition, a "testa" "test" rack verification" must be run each day of use.

RUNNING CONTROLS:

Streck controls are stored in the serology refrigerator. They must be brought to room temperature before use. Open vials are stable for 95 days at room temperature or in the refrigerator. For vials removed from the refrigerator, allow 20-30 minutes for temperature equilibration. Mix vials by inversion and vigorously rolling upright between palms until red

Policy Title	Sedimentation Rate (Streck- ESR Auto Plus)	Policy #	HEM131016
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cells are completely suspended. Continue mixing for 90 seconds. The samples may be placed on an automated rotator prior to use.
If mixed vials sit for more than 1 minute, they must be remixed or the results may be invalid, and the entire bottle may render false levels.

Wipe threads of vial and cap. Recap the tubes tightly.
Store the open vials at room temperature (18-30 degrees Centigrade)
When control values are within the Expected range, patient values can be reported with assurance. When a new lot is received, 20 qc samples should be run to establish this laboratories own mean. The new lot must also be registered- see procedure manual for further instructions.

RACK VERIFICATION:

The test rack contains a series of precise plastic rods with simulated ESR values. The instrument will read each rod and compare it to an internal reference. This is performed once per 24 hour period by night shift.

1. Press NOT OKAY to access the main menu
2. Enter selection number 5 then the instrument will tell you to put the rack verifier into the machine.

SOURCES OF ERROR:

1. Sample not mixed properly.
2. Calibration factor is incorrect.
3. Tube is overfilled or underfilled.
4. Paper label is obscuring the reading.
5. Instrument set up with wrong tube type.
6. Printer paper is empty.
7. High temperature warning, temperature in lab is above 26 degrees C.

The test should be set up within 2 hours after the blood sample is obtained. On standing, erythrocytes tend to become spherical and less inclined to form rouleaux, thus retarding the ESR.

V. REFERENCES

Todd, Sanford, and Davidson, "Clinical Diagnosis and Management by Laboratory Methods"
Streck Laboratories, Inc. ESR-Auto Plus Operator and Technical Manual.

VI. STAKEHOLDERS

N/A

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
Responsible	Laboratory Director	Revised/Reviewed	08/20/2020 10/26/2022

I. PURPOSE

The Diagnostica Stago STA/Compact is the main coagulation instrument providing PT, PTT, Fibrinogen and d-dimer testing. The measurement is based on a mechanical method using electromagnetic sensors.

II. POLICY

This is the primary instrument for performing PT, PTT, Fibrinogen and D Dimer assays.

III. DEFINITIONS

N/A

IV. PROCEDURE

The Diagnostica Stago STA/Compact is an automated coagulation instrument used for in vitro testing of the coagulation system. The instrument is capable of measuring coagulation studies by three modes which include clotting, chromogenic and immunologic assays. Clotting tests are detected by an electromagnetic mechanical clot detection system consisting of a steel ball in each cuvette. The oscillation of a steel ball within the cuvette with the reagents and plasma is monitored by the instrument. When the oscillation of the steel ball is stopped by clot formation, the sensor registers the time. The chromogenic assays are based on the absorbency (OD: optical density) of monochromatic (405 nm) light passing through the cuvette as the reaction occurs. The immunologic assays use the same principle as the chromogenic assays except the light source filter is set for 540 nm.

COAGULATION TESTING

PT/PTT/FIBRINOGEN/QUANTITATIVE D DIMERS

STAGO STA/COMPACT

A. SPECIMEN:

1. Citrated blood in a 3.2% sodium citrate tube only is acceptable.
2. Centrifuge within 1 hour to obtain a platelet poor plasma sample of less than 10 platelets
3. If using a syringe, blood must be added to the tube within 1 minute of completion of draw. The tube must be inverted at least four times. The PT/PTT is not affected if tested on the first tube drawn.
4. Reject clotted specimens, or collected in the wrong anticoagulant.
5. Unopened PT and DVT specimens should be kept at room temperature and be tested within 8 hours from collection.
6. APTT specimens on nonheparinized patients should be kept at room temperature and tested within four hours of collection, and PTT_H (for patients on heparin therapy) should be tested within 2 hours.

B. REAGENTS AND EQUIPMENT:

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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Diagnostica Stago COMPACT
 STA Cleaner Solution (Wash)
 STA cuvettes
 Desorb wash solution-reagent bottle needed to run (in product drawer)
 Follow instructions for each test in each specific procedure.

C. CALIBRATION:

Follow instructions specified in each procedure.

D. QUALITY CONTROL:

1. Two levels of controls are run for each test. See each procedure for specific control instructions.
2. Controls must be run on each time a new reagent is reconstituted.
3. QC must be run each shift of use.
4. If the controls are outside the ± 2 sd range, the instrument will audibly and visually alarm the operator. The quality control values can be found in the Calibration/Quality control files, highlighting the Quality Control in dark blue, and hitting enter then enter for each individual test. All results for a 24 hour period will be converted to a "mean" value at midnight.
5. Sign off the QC in the COAG binder as well as documentation for any out of control or quality control warnings.
6. If the controls do not perform as expected, methods to use to solve the situation include: rerunning the controls, reconstituting new controls and or reagent, checking that the reagent was properly made up and has the appropriate reducers or stir bars if necessary, performing maintenance on the instrument (including flushing the needles if needed), calling the hot line for additional suggestions.
7. If the controls still will not come in as expected, do not report patient's results from the instrument. Send out testing to Dominican Hospital and leave documentation as to what was done.

E. Procedure for Checking Reagent availability:

1. Escape to the MAIN MENU, go under STATUS and arrow down to PRODUCTS to check and see what reagents are ON BOARD and may outdate during your shift. You may print this screen by hitting ALT and PRINT SCREEN simultaneously.
2. Reconstitute the reagents and controls you will need for your shift. PT, PTT are run every shift. Fibrinogen and D Dimer are only run if needed.
3. After the reagents have sat for the required 30 minutes, open the reagent drawer (hit F2 or go to Loading hit enter, arrow down to Products)
4. Check to see the requirements for each reagent have been met, that is, add a reducer if needed or a stir rod if needed.
5. Immediately place in the drawer, Neoplastine C plus (PT reagent) needs to be placed in a circled number place due to the stir rod. All other reagents can in any position. Make sure the red light comes on after you place the bottle in the drawer.
6. Remove any reagents with blinking or no red lights.
7. Do not pick up any reagents. Picking a reagent up will remove it from the instrument. If a red light is not evident next to the reagent, the instrument does not acknowledge that the reagent is on board. To see the type of reagent in each space, look at the screen under "position" (pos) All the reagents are placed in the PRODUCT drawer number two EXCEPT OWRENS BUFFER.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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- Owren's buffer is used as a diluent for fibrinogen and d dimer, and is placed as a reagent in drawer number one or the patient's sample drawer.

F. Ordering and running QC:

- Escape to the MAIN MENU, arrow over to Calibration/Quality Control and hit enter.
- Arrow down to the QUALITY CONTROL- (it is chosen when it is in dark blue.)
- Place the cursor on each test requested and hit F1- (do not press enter key) When all the tests are selected, hit F10 to run- then escape to start the instrument. You will have to enter the password of "QC" when prompted.
- The instrument should return to the "sample" screen with the QC requested on the right side of the screen with the words "running" and a time of completion on the top.
- If there is not enough reagent or the reagent is expired or has no solid red light next to it, the instrument will say "Blocked sample pipetting" and not run.
- The Quality Control File must be printed every night before midnight. Escape to the MAIN MENU, arrow to CALIBRATION/QUALITY CONTROL and select quality control. Place the cursor on each test, PT, PTT, Fibrinogen and D dimer, individually and hit enter, then F1 followed by F6, select EXECUTE then press enter to print each individual values for each test. Press the ESCAPE key to exit, back to the graph, then F2 to change levels, then escape twice and arrow to the next test. All individual data points are converted into one mean at midnight. QC must be printed prior to midnight to verify that it was run.

G. Ordering and running PATIENT SAMPLES:

- The Stago Start can be run in either the MANUAL or AUTO – teleloading or interfaced mode.
- To change modes, escape to the MAIN MENU, arrow to LOADING then SAMPLE hit the ESCAPE key for more options, then arrow up to AUTO or MANUAL and enter.
- Under the MANUAL mode, you can bar code the sample but you have to manually order the specific test.
- Under the AUTO mode, you can bar code the sample and it will automatically run the correct test, but you cannot order a repeat or alternate test with this screen. (* under the AUTO mode the test will automatically be done if the interface is up and working AND the specimen has been received. If the interface is down, and you want to use the auto mode, you have to FIRST BAR CODE THE PATIENT- then go to FILES- Confirm/printouts/transmission, then arrow to specific SAMPLE and ENTER and hit F5 insert to ADD a test or F3 to rerun, then F10 to SAVE then ESCAPE
- If the interface is up and working, and the specimen was received, the test will automatically cross over to the LIS interface under #4. Work with analyzer results, under STAGO in the LIS.

COAGULATION TESTING

PROTHROMBIN TESTING

STAGO COMPACT

PROTHROMBIN TIME:

I. PRINCIPLE:

The Prothrombin time is a basic coagulation screening test for the assessment of congenital and acquired deficiencies of the extrinsic pathway (factors II, V, VII, X). The prothrombin time can be

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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prolonged in certain clinical states, for example use of warfarin, intestinal reabsorption disorders, liver failure, fibrinolysis and DIC.

Prothrombin time is the time required to clot a blood specimen once exposed to a thromboplastin reagent material (containing tissue factor from rabbit brain and calcium). The Stago Neoplastine C Plus has a lot specific ISI (refer to each lot's package insert). This reagent also has a specific heparin inhibitor.

Warfarin (coumadin) is monitored by the prothrombin test because of the test's sensitivity to concentration changes in the vitamin K dependent factors of II, VII and X. Because of the variability of results from different thromboplastin reagents and different instrumentation, it is recommended that the prothrombin time in seconds be converted and evaluated by the INR (International Normalized Ratio). The INR corresponds to the value of the ratio of the patient's Prothrombin time in seconds, and the geometric mean of the normal reference population raised to the value of the ISI (International Sensitivity Index) power.

II. SPECIMEN:

Follow the above procedures under I. Start up, note that PT testing must be completed within 8 hours with UNOPENED tubes.

III. REAGENTS AND SUPPLIES:

STA COMPACT

WASH solution (cleaner)

Cuvettes

Desorb reagent on board

Neoplastine C plus reagent – reconstituted with entire bottle of “reagent 2 – solvent” wait 30 minutes, add one small clean stir bar, and a maxi reducer- make sure the stir bar does not introduce any contamination by thoroughly washing it in distilled water and Desorb if necessary, then dry.

STA Coag Control N and ABN

IV. PROCEDURE FOR CALIBRATION (NEW LOT ONLY):

The prothrombin time is automatically calibrated with each new lot of reagent using the bar coded insert sheet. Simply go into Calibration, PT, and bar code the insert sheet. New lots of thromboplastin reagent, received annually, must have new reference ranges assessed, as well as a crossover with the previous lot and a new mean for the quality control results. The new geometric mean of the normal range must be entered before the quality control can be run. The ISI will be entered with the bar coded calibration sheet for each lot. Call the hot line and refer to the operator's manual for exact instructions.

V. QUALITY CONTROL

1. Two levels of quality control must be run every shift, within 30 minutes of 0300, 900, 1500 and 2100.
2. Neoplastine C plus reagent – transfer the entire contents of reagent two into the freeze dried thromboplastin in reagent bottle one. Allow the reconstituted reagent to stand at room temperature for 30 minutes. Swirl the reagent one vial gently to obtain a homogenous suspension. Then, add a clean small stir rod to the vial, and a maxi reducer, and close with the white perforated cap (WITHOUT THE GREY RUBBER STOPPER!)

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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3. Escape to Loading-F2,, and the product drawer should open, then bar code the newly reconstituted bottle of PT reagent, hit ENTER then place in a CIRCLED NUMBER position in the drawer. ENSURE THAT A RED LIGHT COMES ON NEXT TO THE POSITION! Make sure the bottle is fully seated into the drawer.
4. Escape to the MAIN MENU, then arrow to CALIBRATION/QUALITY CONTROL, then arrow down to QUALITY CONTROL (making the words "quality control" dark blue). With the cursor on PT, hit F1 to select, then F10 to run, then enter QC as a password, then escape to start.
5. The screen will automatically switch to the Sample screen, giving you to time of completion of the tests. To view the completed tests, escape back to the main menu, arrow to calibration/quality control, arrow to quality control, place the cursor on PT, press enter, the Levy Jennings screen will pop up, press F1 for the specific results. Press F2 to change levels, and then F1 to view the second level of control, escape and enter to quit. All quality control results will be automatically reduced to one "mean" value at midnight. Individual results from a previous day cannot be accessed once they have been recalculated into the daily mean so print out the quality control and save in the daily qc binder prior to running for first time each day.
6. Quality Control results must be printed out prior to midnight, by escaping to the MAIN MENU, under CAL/CONTROL, select QUALITY CONTROL, cursor to the PT test and press ENTER, to view the Levy Jennings chart. Press F1 to view the results in tabular form, then press F6 and select execute , and press ENTER to print each individual value for each level. Press F2 (or F3) for other levels and continue with F1 to view, then F6 to print the result. This is the only method of printing out the quality control results. Individual quality control is inputted and accepted into the LIS.

VI. PATIENT TESTING:

1. Load the patient's sample into the F1 Sample drawer by either pressing F1 or going to LOADING, arrowing down to Samples and pressing enter.
2. Make sure F8 microsample has not been entered! Check there is no "u" next to the position. (Microsample is only used with the tall metal holder and the plastic microinsert).
3. After the drawer opens, bar code the sample, and then press ENTER and immediately place in the drawer. In the AUTO MODE (teleloading) the test will automatically be ordered.
4. Make sure the tube is fully seated and that the red light comes on next to the tube (remember that PT reagent needs a stir rod and a plastic straw-like reducer)
5. As soon as the sample drawer closes, the TEST STATUS screen will appear. If there is not enough reagent to run the test, the suspect reagent will appear in red with the amount of the deficiency. This deficiency will BLOCK THE SAMPLE PIPETTING. When this occurs, add the necessary reagent to run the samples by responding N (No) to the warning message "New tests are delayed- reactivate?" Reagents can then be loaded in the drawer.
6. If you respond Y (YES) to the warning message "New tests are delayed- reactivate?" the instrument will continue to perform all tests for which there is sufficient reagent.
7. Alternatively, the instrument can be switched to MANUAL MODE by ESCAPING to the MAIN MENU, arrowing over to LOADING, enter, arrow to SAMPLE, enter, hit ESCAPE for more options, then arrow up to AUTO or MANUAL modes, and entering. Tests can be ordered when the instrument is in the Manual mode while you are bar coding and entering the tube, otherwise, if the instrument is in AUTO- teleloading mode, you cannot add tests under the F1 sample drawer screen, but must go to the FILE, CONFIRMATION/PRINTING/TRANSMITTING, place the cursor on the patient sample you wish to order a test on (it must be bar coded first under the F1 sample screen) then using the F6 INSERT – then ordering the test, or F3 RERUN keys followed by the F10 SAVE key, and escape back to run.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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8. Results will come across the interface and can be chosen with a "1" under the F4 interface screen, then checked for previous results with a F8 under the LIS computer, then verify with a F10.
9. The INR is calculated on the Stago instrument, and will come across once you press enter on the LIS. (The ISI was entered with the insert sheet barcode under calibration when the lot was set up, the mean of the normal range or reference time is also found under the calibration screen and is entered at each lot change.)
10. For results >120 seconds, check for a clot in the tube, and if there is not one present, report as >120 seconds.

COAGULATION TESTING

PTT TESTING

STAGO COMPACT

ACTIVATED PARTIAL THROMBOPLASTIN TIME:

I. PRINCIPLE:

The Activated Partial Thromboplastin Time is a basic coagulation screening test of the intrinsic coagulation pathway (factors XII, XI, IX, X, VIII, V, II and I) The APTT can be elevated in congenital and acquired deficiencies of these factors and also can be used to monitor unfractionated heparin. A prolonged APTT can also be seen in liver disease, consumptive coagulopathy, and in circulating anticoagulant and treatment with thrombin inhibitors like hirudin or argatroban. The APTT involves the recalcification of plasma in the presence of a standardized amount of cephalin (platelet substitute) and a particulate activator (silica.)

II. SPECIMEN:

1. Follow the directions above in the Stago Compact I. START UP.
2. APTTs must be run within 4 hours.
3. APTTs from patients on heparin therapy must be run within 2 hours.

III. REAGENTS AND EQUIPMENT

STAGO COMPACT

WASH solution (cleaner)

Cuvettes

Desorb reagent bottle kept in product drawer

PTT-A Stago reagent- reconstitute with 5 ml of distilled water, allow material to stand at room temperature for 30 minutes then swirl gently, remove the inner grey rubber stopper, replace the white perforated cap. This material is stable for 24 hours on the Stago Compact

Calcium Chloride 0.025 M this material is stable for 72 hours on the Stago Compact

STA Coag Control N and ABN

IV. PROCEDURE FOR CALIBRATION:

There is no calibration for this test.

V. QUALITY CONTROL:

1. Two levels of quality control must be run every shift, within 30 minutes of 0300, 900, 1500, and 2100.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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2. PTT-Automate- Reconstitute with 5 ml of reagent grade distilled water. Let sit for 30 minutes, and swirl gently. This reagent is stable on the instrument for only 24 hours.
3. Reconstitute the Normal and Abnormal quality control bottles with 1 ml of distilled water each. Let sit for 30 minutes.
4. After 30 minutes, load the reagents and quality control materials into the product drawer. Either escape to the main menu and press Loading, arrow to Products or just press F2. Once the drawer is open, bar code the newly reconstituted tubes, press enter and place them anywhere in the drawer where they fit. Make sure the red light comes on next to the reagent.
5. To order quality control, escape to the main menu, arrow over to Calibration/Quality Control, enter. Arrow down to Quality Control, arrow to the test you want and hit F1 to choose, followed by F10 to save, and enter the access code of "QC", then Escape to start the run.
6. After the run is done, it will not print out. To view, go back to the Calibration/Quality Control screen, cursor to each test, hit enter, then F1 for the specific data, escape back and hit F2 for next level, then F1 for results, escape and hit enter at quit then cursor to next test. Accept in LIS.
7. Quality Control results must be printed out each night before midnight—.

VI. PATIENT TESTING:

1. Escape to MAIN MENU, go under STATUS, and arrow down to PRODUCTS to check and see what reagents are ON BOARD and what may outdate during your shift. You may print this screen by pressing ALT/PRINT SCREEN.
2. Reconstitute the reagents and controls you will need for your shift for PT and PTT. Fibrinogen and D Dimer are only run if needed.
3. RUN QC AT 0300, 900, 1500, 2100.
4. After the reagents have sat for the required 30 minutes, open the reagent drawer (hit F2 or go to LOADING , hit ENTER, arrow down to PRODUCTS)
5. Load the patient's sample into the F1 SAMPLE DRAWER by either pressing F1 or going to LOADING, arrowing down to SAMPLES and pressing enter.
6. After the drawer opens, bar code the sample, and then press ENTER and immediately place in the drawer. In the AUTO MODE (teleloading or host interface on) the test will automatically be ordered. (Make sure F8 microsample has not been chosen! If it was, there would be a u next to the sample position.)
7. Make sure the tube is fully seated and that the red light comes on next to the tube.
8. As soon as the sample drawer closes, the TEST STATUS screen will appear. If there is not enough reagent to run the test, the suspect reagent will appear in red with the amount of the deficiency. This deficiency will BLOCK THE SAMPLE PIPETTING. When this occurs, add **the necessary reagent** to run the samples by responding N (NO) to the warning message "New tests are delayed- reactive?" Reagents can then be loaded into the drawer and controls run.
9. If you respond Y (YES) to the warning message "New tests are delayed- reactive?" the instrument will continue to perform all tests for which there is sufficient reagent.
10. Alternatively, the instrument can be switched to MANUAL MODE by ESCAPING to the MAIN MENU, arrowing over to LOADING, enter, arrow to SAMPLE, enter, hit ESCAPE for more options, then arrow up to AUTO or MANUAL modes, and enter. Tests can be ordered when the instrument is in the MANUAL MODE while you are bar coding and entering the tube, otherwise, if the instrument is in AUTO- TELEPORTING mode, you cannot add tests under the F1 sample drawer screen, but must go to the FILE, CONFIRMATION/PRINTING/ TRANSMITTING screen, place the cursor on the patient sample you wish to order a test on (it must first be bar coded under the F1 sample screen) then using the F6 INSERT, arrowing to test and entering, or press the F3 rerun key all followed by the F10 SAVE key twice , and escape.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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11. Results will come across the interface and can be chosen with a "1" under the F4 interface screen, then checked for previous results with a F8 under the LIS computer, then verifying with a F10.

**COAGULATION TESTING
FIBRINOGEN TESTING
STAGO COMPACT**

FIBRINOGEN

I. PRINCIPLE:

This method uses the Clauss method of detecting fibrinogen. In the presence of an excess of thrombin, the clotting time of diluted plasma is inversely proportional to the level of plasma fibrinogen. Once the clot is detected, the time is read from an internal curve that was entered via bar code from the insert sheet. This reagent has a specific heparin inhibitor to allow for testing heparinized plasma samples (up to 2 IU/ml). An increase of fibrinogen level is seen in diabetes, inflammatory syndromes and obesity. A decrease of fibrinogen level is seen in DIC, fibrinolysis, thrombolytic therapy and hereditary diseases. The instrument automatically converts the results in seconds from a standard curve (log-log) to mg/dL. The assay uses a dilution of 1:20 sample plasma to buffer. The instrument automatically dilutes this sample to a 1:8 dilution on sample with a concentration of less than 150 mg/dL or a 1:40 dilution if the value is greater than 900 mg/dL. If the auto redilute feature was used, the results are displayed on the screen in BLUE instead of the normal BLACK numbers.

II. SPECIMEN:

Follow the above procedures under I. START UP; note that fibrinogen tests must be completed within 8 hours.

III. REAGENTS AND SUPPLIES:

STA COMPACT

WASH solution (cleaner)

Cuvettes

Desorb reagent on board

Owren's Buffer- ready for use, place in sample drawer (F1) and enter F1 for diluent, stable for 72 hours

Fibrinogen-5- reconstitute with 5 ml of distilled water, replace white perforated cap without grey rubber stopper, then let stand at room temperature for 30 minutes, then swirl gently, stable for 5 days on the COMPACT

STA Coag Controls N and ABN

IV. PROCEDURE FOR CALIBRATION:

1. Fibrinogen kits are precalibrated and are all identical for all vials of each lot.
2. To enter the data for the calibration curve, after you scan a new lot of fibrinogen reagent, the instrument will ask you to scan the bar codes on the insert sheets.
3. The calibration curve will be validated when both levels of fibrinogen control levels are run. To review the curve, escape to the main menu, then arrow to Calibration and enter, move the cursor to FIB and enter.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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V. QUALITY CONTROL:

1. Two levels of quality control must be run every shift a fibrinogen test is run.
2. Reconstitute fibrinogen with 5 ml of distilled water, let sit for 30 minutes then swirl. Recap with the white perforated cap, without the rubber stopper and place on instrument. It is stable for 5 days. Owren's Buffer is already in the ready to use liquid form and is good for 72 hours on the instrument.
3. Enter F2 to open the product drawer to place the fibrinogen reagent with the white perforated cap on in the product drawer, bar code the bottle, hit enter and place in drawer two, ensure it is sitting correctly and that the red light comes on.
4. Enter F1 to open the sample drawer to place the Owren's buffer in the sample drawer. Bar code the bottle, and choose F1 diluent, then enter and place the bottle in the back of drawer number one in position number 8, make sure the bottle is level and fully seated and that the red light comes on.
5. Reconstitute the normal and abnormal levels of Stago control with 1.0 ml of distilled water, let set for 30 minutes, swirl gently.
6. Press F2 to open the product drawer, remove any old control material and any bottle with a blinking red light. Bar code the control bottle, enter and place in drawer number two, watching for the red light to come on.
7. Under Calibration/Quality Control, arrow down to quality control, enter and choose tests you need to run controls on by hitting "F1", then F10 to save, entering the password of "QC" enter, then escape to begin your run.

VI. PATIENT TESTING:

1. Load the patient's sample into the F1 Sample drawer by either pressing F1 or Going to LOADING, arrowing down to Samples and hitting enter.
2. After the drawer opens, bar code the sample, and then hit ENTER and immediately place in the drawer. In the AUTO MODE (teleloading) the test will automatically be ordered.
3. Make sure the tube is fully seated and that the red light comes on next to the tube.
4. As soon as the sample drawer closes, the TEST STATUS screen will appear. If there is not enough reagent to run the test, the suspect reagent will appear in red with the amount of the deficiency. This deficiency will BLOCK THE SAMPLE PIPETTING. When this occurs, add the necessary reagent to run the samples by responding N (No) to the warning message "New tests are delayed- reactivate?" Reagents can then be loaded in the drawer and controls ordered and run. If you respond Y (YES) to the warning message "New tests are delayed- reactivate?" the instrument will continue to perform all tests for which there is sufficient reagent.
5. Alternatively, the instrument can be switched to MANUAL MODE by ESCAPING to the MAIN MENU, arrowing over to LOADING, enter, arrow to SAMPLE, enter, press ESCAPE for more options, then arrow up to AUTO or MANUAL modes, and entering. Tests can be ordered when the instrument is in the Manual mode while you are bar coding and entering the tube, otherwise, if the instrument is in AUTO- teleloading mode, you can not add tests under the F1 sample drawer screen, but must go to the FILE, CONFIRMATION/PRINTING/TRANSMITTING, place the cursor on the patient sample you wish to order a test on (it must be bar coded first under the F1 sample screen) then using the F6 INSERT – then ordering the test, or F3 RERUN keys followed by the F10 SAVE key, and escape back to run .

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
---------------------	--------------------------------------	-----------------	-----------

- Results will come across the interface and can be chosen with a "1" under the #4 interface screen, then checked for previous results with a F8 under the LIS computer, then verified with a F10.

VII. LIMITATIONS:

- If the fibrinogen results are not between 150 and 900 mg/dL, the instrument will automatically make another appropriate dilution. If the results are less than 150 it will remake a 1:8 dilution. If the results are greater than 900, it will automatically make a 1:40 dilution. The instrument is linear from 60 to 1500 mg/dL.
- >Mmax or V>Vmax will be the initial result on the testing screen if the results are extremely low, then the instrument will automatically make a 1:8 dilution and rerun (this is because it is an inverse curve.)
- <Mmin will be the initial result on the testing screen if the results are extremely high, then the instrument will automatically make a 1:40 dilution.
- The results will be in black numbers if they are between 150 and 900 and the normal dilution was used and in blue numbers if a higher or lower dilution was necessary.
- In patients receiving drugs that affect the fibrinolytic system, the plasma levels of fibrinogen degradation products may be extremely high. FDPs may inhibit both thrombin action of fibrinogen and fibrin polymerization. At normal fibrinogen concentrations, FDPs have a minimal effect on the fibrinogen assay. At fibrinogen concentrations below 150 mg/dL, FDPs greater than 140 ug/mL increasingly inhibit the thrombin clotting rate assay. High levels of paraproteins may interfere with the polymerization of fibrin monomers.
- Fibrinogen testing on the Stago Compact is insensitive to the following substances: fibrin degradation products (up to 130 ug/mL), hirudin (up to 3 ug/mL) or heparin (up to 2 IU/mL.)
- Call the hotline if the instrument is not performing as you expect.

COAGULATION TESTING

QUANTITATIVE D- DIMER ASSAY

STAGO LIATEST

IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER

STAGO COMPACT

AUTOMATED QUANTITATIVE D-DIMER TESTING:

I. PRINCIPLE:

The STA- LIATEST- D-DIMER is a quantitative immuno-turbidimetric method to determine d-dimer in plasma. It is used in assessing deep vein thrombosis and pulmonary embolism disease; however, elevated levels are also seen in inflammatory responses, infection, surgery, trauma, DIC, pregnancy, MI or liver/kidney disease. The test is used as a negative predictor for DVT or PE, as negative results only have value in ruling out clotting disorders.

The coagulation system consists of the formation, then degradation of a fibrin clot. This degradation process is called fibrinolysis. Plasmin is the enzyme that breaks apart the fibrin clot. Plasmin is made from the inactive plasminogen that is activated by tissue plasminogen activator (TPA) or other activators like urokinase. Plasmin acts on the fibrin clot to break it into various d dimer particles or products. Antibodies have been made that are specific for these fibrin degradation products. The presence of these various fibrin degradation products, among which

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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D-Dimer is the terminal product, is the proof that the fibrinolytic system is working to dissolve the fibrin clot.

Clinical applications for this test are as follows: Disseminated Intravascular Coagulation (DIC), negative predictor for the diagnosis of a thrombotic episode (i.e. DVT or PE), efficacy of treatment for a thrombotic episode and screen for possible re-occurrence (MI), and screen for other activation states of coagulation for example post-operative, cancer or cirrhosis.

The instrument uses a beam of monochromatic light which is projected through a suspension of the patient's plasma and microlatex particles with antibodies attached to them. If the wavelength of light is greater than the diameter of the latex particles, the light is only slightly absorbed. In the presence of the antigen being tested for, the antibody-coated latex particles agglutinate to form aggregates of a diameter greater than the wavelength of the light; more of the latter is absorbed. This increase in light absorption is a function of the antigen level present in the test sample.

II. SPECIMEN

1. Follow the above procedure under I. Start up,
2. Only Citrated blood 3.2% sodium citrate.
3. Test specimen within 8 hours.
4. Reject specimens that are short draws, clotted, lipemic or hemolyzed.

III. REAGENTS AND EQUIPMENT

Centrifuge

STA- Owren-Koller Buffer

STA mini Reducer

STA-COMPACT

STA-LIATEST Kit including buffer and latex:

1. Buffer: ready to use. Allow the reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Add a mini-reducer straw to the bottle, and affix the white perforated cap without the inner red rubber stopper. Place bottle in drawer two, (hit F2, bar code bottle, hit enter then place in the middle drawer.) buffer reagent is good on board for 15 days.
2. Latex: ready to use. Suspension of microlatex particles coated with two different mouse monoclonal anti-human D-dimer antibodies. Allow reagent to stand at room temperature for 15 minutes, mix gently without creating bubbles. Use a mini reducer and replace the white perforated cap without the rubber stopper. Place the reagent in the middle product drawer by entering F2, barcoding the bottle, then pressing enter and then placing the bottle in the second drawer, making sure the bottle is fully seated and the red light comes on.
3. STA Liatest Controls N and P (negative and positive) two plasmas containing different levels of D Dimer. Reconstitute each bottle with 1 ml reagent grade DI water. Let sit 30 minutes at room temperature. Swirl gently. Reconstituted reagent is good on instrument for 8 hours.

IV. PROCEDURE FOR CALIBRATION:

1. The reagent is pre-calibrated: this calibration is the same for all the reagents of each lot.
2. To enter the data for the calibration curve: The STAGO COMPACT monitors the lot numbers and knows the current lot number and its calibration. When the operator scans the bar code for the new lot of D-dimer reagent, the Compact will request the operator to scan the bar codes printed on the package insert.

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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3. The calibration curve will be validated for the lot being used once the two Liatest D Dimer controls have been run. If the validation controls are outside the assayed range, the Compact will not run the patient samples.
4. To check the calibration curve on the screen, go to MAIN MENU under CALIB/CONTROL and select CALIBRATION. Move the cursor to D-Dimer and press enter.
5. To print this curve, while the d- dimer calibration curve is on display, press ESCAPE, select the PRINT option and hit ENTER. Select EXECUTE, then ENTER.
6. Print out and keep in the quality control binder all calibration curves for each new lot of reagent.

V. QUALITY CONTROL

1. Two levels of Liatest quality control N and P must be run when there is a d dimer test requested on a patient.
2. Escape to the MAIN MENU, arrow to STATUS, arrow down to PRODUCTS to check and see what reagents are ON BOARD and not outdated. Reconstitute more LIASTAT D DIMER if both reagents are outdated. Reconstitute LIASTAT quality control N and P with 1.0 ml of DI water. Let sit 30 minutes.
3. Load the reagents and quality control into the second drawer (F2), scan the bar code on the bottle, hit enter then place in any place in the second drawer that fits the bottle. Make sure the bottle is fully seated and that the red light comes on.
4. To order quality control, escape to the MAIN MENU, arrow over to CALIB/QUALITY CONTROL, enter, arrow down to QUALITY CONTROL, enter, arrow down to the LIATEST D DIMER and press F1, followed by F10 (save) then ESCAPE and enter "QC" as the password to validate, then escape once more to start.
5. After the run is done, go back to the CALIB/QUALITY CONTROL heading, then press enter, and arrow to quality control, then enter, then F1 to view each level , then escape, F2 to see the next level, then F1 for results. Accept results in LIS and record time run in the quality control binder.

VI. PATIENT TESTING

1. Escape to MAIN MENU, go under STATUS, and arrow down to PRODUCTS to check and see what reagents are ON BOARD and what you need to reconstitute.
2. Reconstitute what is needed as per above instructions under reagents.
3. Run the LIATEST QC- N and P if this has not been done on your shift (qc is run only if test is ordered for each shift)
4. Load the patient sample into the F1 drawer either by pressing F1 or by going into LOADING, arrowing down to SAMPLES and pressing enter.
5. After drawer opens, bar code the sample, and then press ENTER and immediately place anyplace in drawer one, In the AUTO MODE, (teleloading or host interface on) the test will automatically be ordered.
6. Make sure the tube is fully seated and that the red light comes on next to the tube.
7. As soon as the sample drawer closed (enter to close) the TEST STATUS screen will appear. If there is insufficient reagent to run the test, the suspect reagent will appear in red with the amount of the deficiency. This deficiency will BLOCK THE SAMPLE PIPETTING> When this occurs, add the necessary reagent to run the samples by responding N (no) to the warning message, and then add the reagents.
8. Alternatively the instrument can be switched to MANUAL MODE by ESCAPING to the MAIN MENU, arrowing over to LOADING, enter, arrow to SAMPLE, enter, hit ESCAPE for more options, then arrow up to AUTO or MANUAL modes, and enter. Tests can be ordered when

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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the instrument is in the manual mode while you are bar coding and entering the tube, otherwise, if the instrument is in auto- teleloading mode, you cannot add tests under the F1 sample drawer screen, arrow to FILE/CONFIRMATION – PRINTING TRANSMITTING screen place the cursor on the patient sample you wish to order a test on (it must be bar coded first under the F1 sample screen) then using the F6 insert arrowing to test and entering, or press F3 rerun key – all are followed by F10 SAVE key twice, and then ESCAPE. Results will come across the LIS interface.

REFERENCE RANGES:

Results of less than 225 ng/mL of D-dimer units is considered negative. Values above 225 may be due to any inflammatory and diseased process, including DVT or PE. This test is only used to RULE OUT clots, positive results are not predictive.

The following caveat is printed with each d dimer test:

“D-Dimer (DDDVT) results below the manufacturer’s cutoff of 225 ng/mL D-Du MAY BE CONSIDERED A NEGATIVE PREDICTOR FOR DVT OR PE. This assay may be used as a negative predictor for DVT/PE with CONSIDERATION OF CONDITIONS THAT CAN ALTER THE VALUES OBTAINED BY THIS ASSAY. Co-morbid conditions which can increase D-Dimer include surgery, trauma, infection, inflammation, DIC, pregnancy and delivery, MI, liver/kidney disease. Anticoagulation therapy can DECREASE D-Dimer values. “

VII. LIMITATIONS AND INTERFERING SUBSTANCES:

1. Cloudy plasmas may lead to an under-estimation of the D-Dimer level. Ensure that the absorbance value at 540 nm of the plasma diluted 1:6 with Owren’s Koller Buffer is <.35
2. FDP concentrations greater than 15ug/mL may lead to an overestimation of D-Dimer.
3. The presence of rheumatoid factor at a level greater than 50 IU/mL may lead to an over-estimation of the D-Dimer level.
4. The D-Dimer is insensitive to fibrinogen and the E fragment. A low cross reactivity is observed with the D fragment.
5. D-Dimer is insensitive to hemoglobin (up to 5 g/L), bilirubin (up to 200 mg/L, unfractionated heparin (up to 2 IU/ml) LMWH (up to 2 anti-Xa IU/ml.)
6. Linearity for D-Dimer is 110 to 2000 in the regular mode, if results are higher (printout says >Mmax), you should rerun in the D-DI x5 mode.

VIII. WEEKLY MAINTENANCE

1. **Clean two air filters:** (one located on the back, left of instrument & one located on the right, inside)
2. **Pass needles using mandrels:** from the main menu, go to maintenance and enter, use the arrow down key to reach maintenance again and enter, press enter on needle purge, press F6 to open the drawer, raise the transparent panel, and pas the stylet thru the 3 needles
3. **Clean washing wells:** use 1:10 diluted bleach (1 volume 5% sodium hypochlorite w/ 9 parts H2O) fill the 3 white wells in the white block $\frac{3}{4}$ full, close the transparent cover, press F6 to close the drawer and allow the needles to soak in the bleach for 10 minutes.
4. **Perform needle purge:** Press F1 to purge needle #1, F2 to purge needle #2, F3 to purge needle #3, press Esc, then “y” to pop-up screen
5. **Clean suction tip:** Press the down arrow key 3 times to suction tip replacement and then enter 2 press F10 to continue, raise the transparent panel & take out the cuvette bin (while out, empty it), remove the grey suction tip & clean it with a swab moistened with water, then reassemble by placing the suction tip back, reinserting the waste bin and closing the

Policy Title	Stago Compact Coagulation Instrument	Policy #	HEM131017
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transparent cover, press F10 key 2 times and when the pop-up screen says “succeeded,” press space bar key (if it does not automatically do the above or it needs to be repeated, use the arrow down key to suction tip test and press enter), then use the arrow down key to return to the previous menu, and press enter 3 times.

6. **Clean measurement & incubation wells:** Raise the transparent window and check each well with magnetic wand to remove and balls, then use a cotton swab dampened with ethanol (located in micro safety cabinet under hood) to clean each well in the black block, clean the top of this black measurement plate with gauze dampened with water.
7. **Clean sample and product drawers:** from the main menu, press F1 for the sample drawer and clean the top with gauze slightly moistened with water and then repeat with F2 for the product drawer→
8. **Check peltier reservoir:** Open the right side of the instrument to check the liquid level, and if needed, fill with liquid cooling glycol (bottom shelf of large hemo fridge) by **turning instrument off first (from main menu, halt, stop, switch off green button on left, bottom side).
9. **Check ISI:** From cal screen, choose PT with enter and print with ESC-Options-Print

IX. MONTHLY MAINTENANCE

1. Check INR calculation
2. As needed when <50%, replace syringe tip and O ring

V. REFERENCES

Diagnostica Stago Procedure from Disk DSI-TSD-US 6/30/2003 JSS
 STA/COMPACT Operators Manual V. 1.0 1/1996
 NCCLS H3-A3 and H21-A2

VI. STAKEHOLDERS

N/A

Policy Title	Hematology Downtime	Policy #	HEM131020
Responsible	Laboratory	Revised/Reviewed	<u>10/26/2022</u> 1/20

I. PURPOSE:

To test and verify results in hematology and coagulation during a computer downtime.

II. Policy

III. DEFINITIONS:

IV. PROCEDURE:

LH500:

Barcoded specimen: (specimens that have previously been ordered in LIS)

Run thru the instrument as usual per SOP.

No barcode label: (For specimens with a hand-written downtime order)

Use the following procedure in the **manual mode**:

1. Add the specimen to the "TO Do List" by selecting the "patient bed with the + icon" at the top of computer screen and a pop-up box will be displayed. With the mouse, check both the CBC and Diff boxes. In the sample id field and the patient id fields, enter the 3 digit downtime number along with the patient demographics (name, gender, date of birth) and date and time of draw. Click the "patient bed+ icon" on this pop-up to "add this sample request." Run the specimen using the 3 digit downtime number and the printout will print with the entered patient demographics.
2. If a manual differential is required, count the slide off-line and hand-write it on the CBC result printout.
3. Fax the result to the appropriate department and save a copy of the result in hematology.
4. When the computer system is enabled again, the specimens that were run should automatically transmit to the LIS from the instrument. If not, to resend the specimens to the interface use the "computer to computer icon" on the top, far left of the computer screen while on the desired specimen (Arrow keys on right can be used to scroll through patients).

Policy Title	Hematology Downtime	Policy #	HEM131020
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Non-barcoded specimens data will be transmitted with the 3 digit number preceded by 0000 zeros under the patient column. Select the desired specimen with "1," enter the billing number and choose the CBC order (enter the manual diff if needed) and verify the data-

— with a F6 comment that indicates the time the test was performed and the testing CLS's
— initials.

STAGO COMPACT:

1. For barcoded specimen, scan and load the specimen. If the test ordered does not transfer, close the drawer and from the main menu, highlight the accession number, hit enter for a pop-up screen, use "F5 insert" to highlight the desired test, enter, F10 to save, and then ESC to run.
2. Change the instrument to manual mode using "F1" to load samples, then "ESC" Options and use the up arrow to highlight manual mode and enter. Enter the patient's name and date of birth and the test as above.
3. Results will automatically print. Ensure that the full name and date of birth are on the printout. If not, hand write the information along with the patient's location, the date and time of draw and the initials of the CLS that completed the testing.
4. Fax a copy of the results to the ordering department and retain a copy in hematology.
5. To verify results when the computer comes back up:
 - a. If the specimen is still loaded on the instrument, enter on it and select F11, transmit.
 - b. If the specimen is no longer on the instrument, select the Files tab and then confirm/printout/transmit and locate the desired specimen and enter, F11, transmit.

NON-INTERFACED RESULTS:

1. Reticulocytes, sedimentation rates and body fluid counts are to be result on the downtime form as well as the department logs.

V. REFERENCES N/A

VI. STAKEHOLDERS

Policy Title	Delegation of Laboratory Medical Director Responsibilities	Policy #	LAB101
Responsible	Laboratory Director	Revised/Reviewed	09/2020 10/17/2022

I. PURPOSE

The purpose of this policy is to outline the framework for the delegation of responsibilities for planning, directing, coordinating, providing, and improving services to respond to community and patient needs and improve health care outcomes.

II. PRINCIPLE

The Laboratory Medical Director is responsible for the development, implementation and maintenance of the policies and procedures that guide and support the provision of service as defined by The Joint Commission. He/she is responsible for the overall technical and clinical laboratory operations to assure quality patient care services. As this is a very large task, certain responsibilities have been delegated to other qualified members of the laboratory management team. This policy defines the activities and those authorized to act in the Medical Director's behalf.

III. DELEGATION OF RESPONSIBILITIES

For each Laboratory "Activity" or responsibility listed below, the Watsonville Community Hospital "Job Title" followed by the "CLIA Titles" in parentheses designates the primary and secondary delegates. The Laboratory Director departmental responsibilities are as follows:

- A. Oversight of the Clinical Laboratory (Blood Bank, Hematology, Chemistry, and Microbiology).
- B. Oversight of Anatomical Pathology (Cytology and Histology).

ACTIVITY	PRIMARY DELEGATE	SECONDARY DELEGATE
Interprets, correlates and communicates laboratory data.	Pathologists (Lab Medical Director, Clinical Consultant)	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Leads (Technical Supervisors, General Supervisors)
Performs anatomic pathology procedures.	Pathologists (Lab Medical Director, Clinical Consultant)	
Provides consultations regarding the medical significance of laboratory data.	Pathologists (Lab Medical Director, Clinical Consultant)	
Interacts with physicians and/or medical staff	Pathologists (Lab Medical Director, Clinical Consultant)	Administrative Director of Lab Services (Technical Supervisor, General Supervisor);

Policy Title	Delegation of Laboratory Medical Director Responsibilities	Policy #	LAB101
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Interacts with administration, government and other agencies.	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors)
Interacts with patients and their representatives	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Technical Staff (Testing Personnel)
Monitors standards of performance	Pathologists (Lab Medical Director, Clinical Consultant), Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors)
Develops laboratory operating budget	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Lead Techs (Technical Supervisors, General Supervisors)
Monitors QC, including review of QC data	Pathologists (Lab Medical Director, Clinical Consultant), Administrative Director of Lab Services (Technical Supervisor, General Supervisor);	Lead Techs (Technical Supervisors, General Supervisors); Technical Staff (Testing Personnel)

Policy Title	Delegation of Laboratory Medical Director Responsibilities	Policy #	LAB101
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Monitors Performance Improvement (PI)	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Leads – QA (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)
Monitors tests referred to outside laboratories	Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors)
Provides Laboratory education programs	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)
Determines space and other resources required for services including the selection of laboratory equipment and supplies.	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)
Ensures sufficient personnel with adequate documented training and experience, including documentation of competency for testing activities.	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Lead Techs (Technical Supervisors, General Supervisors)
Implements and maintains Point-of-Care Testing program.	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinator – QA (Technical Supervisor, General Supervisor)	

Policy Title	Delegation of Laboratory Medical Director Responsibilities	Policy #	LAB101
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Implements a safe laboratory environment in compliance with good practice and applicable regulations.	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinator – QA (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors); Technical Staff (Testing Personnel)
Performs compliance audits of patient results and billing.	Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)
Reviews, investigates, and follows-up on laboratory errors and unusual events.	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Lead Techs (Technical Supervisors, General Supervisors)
Subscribes to proficiency testing program(s)	Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors)
Performs proficiency testing.	Lead Techs (Technical Supervisors, General Supervisors), Technical Staff (Testing Personnel)	Lab Coordinators (Technical Supervisors, General Supervisors)
Reviews proficiency testing results.	Pathologists (Lab Medical Director, Clinical Consultant); Administrative Director of Lab Services (Technical Supervisor, General Supervisor)	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)

Policy Title	Delegation of Laboratory Medical Director Responsibilities	Policy #	LAB101
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Develops and maintains procedure manuals.	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Lead Techs (Technical Supervisors, General Supervisors)
Maintains instrument maintenance and functions recors	Lab Coordinators (Technical Supervisors, General Supervisors); Lead Techs (Technical Supervisors, General Supervisors)	Technical Staff (Testing Personnel)
Maintains Laboratory Information System, including verification of the reliability of data for patient management, accuracy of calculations, appropriateness of reference intervals, confidentiality of data and preservation of records	Administrative Director of Lab Services (Technical Supervisor, General Supervisor); Lab Coordinators (Technical Supervisors, General Supervisors)	Lead Techs (Technical Supervisors, General Supervisors)

IV. REFERENCES

References and Citations: CAMLAB: Comprehensive Accreditation Manual for Laboratories and Point-of- Care Testing
The Joint Commission Standards
PA Department of Health: Quality Assessment Document
February 2007. CLIA: Subpart M – Personnel for Nonwaived Testing
CLSI. A Quality System Model for Health Care; Approved Guideline.
CLSI Document: HIS-A2; Vol. 24 No. 37, 2004.

V. STAKEHOLDERS

N/A

Policy Title	IQCP General	Policy #	LAB0002
Responsible	VP, Ancillary Services	Revised/Reviewed	09/01/2020 10/17/2022

I. **PURPOSE**

An Individualized Quality Control Plan is Quality Control based on risk management. IQCP is intended to ensure effective QC for each laboratory and the tests it performs. The IQCP policy can be overall or test specific. Each platform must have separate evaluation for each location. Risk is a measure of the severity of impact of a potential error, multiplied by the probability with which an error is likely to occur and your ability to detect the error if it should occur. IQCP consists of the following key components:

Risk Assessment (RA)

Identify & evaluate potential failures and sources of errors in a testing process

- Perform and document a risk assessment that, at a minimum, evaluates potential for an error to occur related to each of these six components:
 - Test/Test Systems – including test name, test kit or system and CLIA category.
 - Testing Personnel
 - Environment
 - Type of Specimen
 - Reagents
 - Post Analytic Process (method of reporting of patient results)
- Assess as follows:
 - Is Error Likely to Occur? (Yes, No or Possible)
 - Would Consequences Be Severe in the Event of an Error? Yes or No
- State your method of Error Prevention.
- Establish the optimum QC Method for each test performed in the laboratory to detect and control potential sources of error (at a minimum, the manufacturer's QC requirements must be followed).
- Monitor the QC plan for effectiveness.

Quality Control Plan (QCP)

Policies/procedures to prevent or reduce the risk and control test quality

All individualized quality control testing must adhere to one or more of the following methods:

- Manufacturer's Quality Control Requirements
- CMS/CLIA requirements of 2 Levels of QC Daily or Current Regulatory Requirements.
- Reduced QC with a risk assessment
- An alternate process that exceeds all Manufacturer's and CMS/CLIA Minimum Requirements

Included in laboratory quality is a process in which all raw QC data is reviewed for compliance, which includes daily, weekly, bi-weekly, monthly, quarterly, bi-annual and annual duties/responsibilities and checks for all tests, instrumentation and quality control in the department.

Procedure

1. Method Performance Specification Review – a detailed documented review of all testing performed in the laboratory must be performed. The review includes:

Policy Title	IQCP General	Policy #	LAB0002
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- Analyte/Test Name
- Test System or Kit
- Implementation Validation - performed and readily available for review?
- Analytical Measurement Range
- AMR Reporting – how to report results outside the analytical measurement range.
- Normal Patient Reference Range
- Critical Values
- Reference Range Established – method to include: Population Study (PS), Manufacturer's Recommendation (MR) or Reference Books (RB).
- Is Linearity Required?
- Linearity Method (if applicable)
- Proficiency Survey Utilized
- QC Material Used – includes QC type, levels and timing.

According to the specific test which IQCP has been performed a Quality Control Plan will be developed. An example for C.Diff is as follows:

Quality Control Plan

The QC frequency must be supported by your Risk Assessment Based on the risk assessment, ease of use of test, staff competency, and external QC data, it is determined that it appropriate to perform external QC when there is a new operator (documented competency on their orientation competency check list), with each new kit, if the technologist questions the kit performance. This will include a positive and negative control provided with the kit. Internal QC is reviewed for proper test performance on each test. Internal QC is blue color in the control reaction port. If there is not detectable blue color in the control reaction port the test is invalid. All staff that perform the test perform external controls periodically.

Based on the risk assessment, it is important to ensure that the test is not left at room temperature for more than 2 hours prior to testing and the specimen is brought back to room temperature prior to testing. To monitor that the specimen temperature was handled correctly, an internal comment field of SPTMP will be added. If the specimen does not meet handling requirements it is to be rejected and recollected.

Based on the risk assessment, it is important to ensure that the sample is mixed prior to testing. Mixing of the specimen will be monitored by adding an internal comment field of MIX.

Kit temperature is important to the quality of the test results. An internal control comment will be added of RGTEMP to document acceptable reagent temperature.

Room temperature and refrigerator temperatures are monitored daily and corrective action is taken as needed.

Personnel must have documented competency for this test prior to performing and reporting results without oversight.

Quality Assurance (QA)

Continuous quality monitoring to evaluate the effectiveness of the IQCP. Closes the loop to your RA and QCP.

Policy Title	IQCP General	Policy #	LAB0002
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Procedure:

IQCP Risk Assessment – using the Method Performance Specification spreadsheet perform a detailed documented quality control review of all testing performed in the laboratory. The review includes Pre-Analytic, Analytic, and Post Analytic:

- Test/Test Systems
 - Analyte
 - Test System or Kit
- Sources of Error
 - Testing Personnel Levels Required (in this laboratory)
 - Environment Adequate (Yes or No)
 - Type of Specimen(s) (list specifically)
 - Reagents
 - K: Contained Kit
 - MPR: Manufacturer prepared Reagents
 - C: Separate Components
 - Post-Analytic Process (Interfaced/Manual Entry Reporting)
 - Risk Assessment
 - Is Error Likely To Occur? (Yes, No, Possible)
 - Would Consequences (of error) Be Severe? Yes or No
 - Method of Error Prevention – This assessment determines the “last line of defense” in error detection. In other words, what is the last step in determining if an error has occurred when all quality control testing is successful? The answer is the result reporting process. What steps do the Testing Personnel take prior to finalizing the result for reporting? And, what retrospective review may be performed to detect erroneous result reporting and provide for timely corrective action?
- Method of Quality Control - Establish the optimum QC Method for each test performed in the laboratory to detect and control potential sources of error (at a minimum, the manufacturer’s QC requirements must be followed).
 - Will follow Manufacturer's QC Requirements
 - CMS/CLIA – Will perform 2 Levels of QC Daily or Current Regulatory Requirements depending upon test/test system.
 - IQCP – Will perform reduced QC based on Risk Assessment
 - QC procedure exceeds all Minimum Requirements of manufacturer, CMS/CLIA and regulatory agencies. Included in this section will be a definition of the actual QC process in place for each test/test system.

Quality Assessment of the IQCP plan must be ongoing as well as annual review by the Medical Director. Below is an example of the C.Diff QA Plan.

Quality Assurance Plan:

The C.Diff Toxin A&B IQCP is monitored by QC records, proficiency testing, patient results review, corrective actions, competencies, temperature charts, turnaround time reports, complaint reports, error logs, and specimen rejection logs. The effectiveness of this IQCP is reviewed annually and updated/changed as needed based on these monitors as listed on the subsequent assessment review sheet. In between annual reviews, if one of the monitors indicates a problem, the IQCP will be reviewed and updated/changed as needed. However at the current time, historical

Policy Title	IQCP General	Policy #	LAB0002
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proficiencies and QC show that current QC practice is adequate. Refer to the C. Diff Toxin A&B policy and Laboratory General Policies for detailed information on the monitors listed above.

The responsibility for ensuring the IQCP meets the requirements to assure the quality of laboratory services provided, identify failures in quality as they occur, and provide equivalent quality testing, resides with the Laboratory Director. The Technical Supervisor is delegated the responsibility for establishing IQCP and performing ongoing assessments, notifying the Lab Director of any issues as part of the laboratory's overall quality control program. The Lab Director may assign, in writing, specific portions of IQCP tasks to other laboratory individuals. However, the Lab Director remains responsible for the IQCP, and all CLIA personnel requirements must continue to be met. Each test system is reviewed continually as a part of ongoing Laboratory Performance Improvement.

II. REFERENCES

1. www.COLA.org
2. mycommunity.chs.net/OS/lab/sitepages/home.aspx
3. Joint Commission 2015 IQCP Webinar
4. TJC Perspectives Articles
5. CMS http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

III. STAKEHOLDERS

N/A

Policy Title	Influenza A & B	Policy #	LAB131031
Responsible	Laboratory Director	Revised/Reviewed	10/26/2022

I. PURPOSE

The ID NOW Influenza A & B 2 assay performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology for the qualitative detection and discrimination of influenza A and B viral RNA in direct nasal or nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. It is intended for use as an aid in the differential diagnosis of influenza A and B viral infections in humans in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

II. PRINCIPLE

Influenza is a highly contagious, acute, viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while Type B infections are usually milder.

Rapid diagnostics with increased sensitivity are essential for the reliable detection of influenza A and B, allowing immediate, effective treatment decisions. Rapid diagnosis of influenza can lead to reduced hospital stays, reduced secondary complications and reduced cost of hospital care, and allow effective implementation of infection control measures.

ID NOW influenza A & B 2 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and differentiation of influenza A and influenza B from nasal swabs and nasopharyngeal swabs (direct and eluted in viral transport media). If the ID NOW instrument is set to "Early Detection", a positive result will be displayed for Influenza A or Influenza B immediately upon detection. The ID NOW instrument has a small footprint and easy to use a graphical user interface for convenience within a busy hospital or point-of-care environment. The ID NOW influenza A & B 2 kit contains all components required to carry out an assay for influenza A and B on the ID NOW instrument.

ID NOW influenza A & B 2 is an automated multiplex assay that utilizes isothermal nucleic acid amplification technology for the differential and qualitative detection of influenza A and influenza B viral nucleic acids. It is comprised of a Sample Receiver, containing elution buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW instrument.

The reactive tubes in the Test Base contain the reagents required for amplification of Influenza A and Influenza B, respectively, as well as an internal control. The templates (similar to primers) designed to target Influenza A RNA amplify a unique region of the PB2 segment while the templates designed to amplify Influenza B RNA target a unique region of the PA segment. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets.

Policy Title	Influenza A & B	Policy #	LAB131031
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To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, mixing and detection are provided by the instrument, with results automatically reported.

III. **POLICY**

The ID NOW Influenza A & B 2 is a CLIA waived test. This policy and procedure is for Clinical Laboratory Scientists, ED Techs, MLTs, and Nurses who have successfully completed initial training and maintained annual competency.

IV. **REAGENTS AND MATERIALS**

1. Test Bases: Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of Influenza A and B viral RNA.
2. Sample Receivers: Blue plastic components containing 2.5mL of elution buffer.
3. Transfer Cartridges: White plastic components used to transfer 2 x 100uL of sample extract from the Sample Receiver to the Test Base.
4. Nasal Swabs: Sterile swabs for use with the ID NOW Influenza A & B 2 Test
5. Positive Control Swab: The positive control swab is coated with inactivated influenza A & B viruses.
6. Negative Control Swab: The negative control swab is coated with inactivated Group C Streptococcus.
7. Plastic disposable pipettes capable of delivering 200uL VTM sample
8. ID NOW instrument

V. **STORAGE**

Store kit at 2-30°C. The ID NOW Influenza A & B 2 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

VI. **SPECIMEN COLLECTION AND HANDLING**

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

1. Nasal Swab:

For optimal test performance, use the swabs provided in the test kit. Alternatively, rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples. Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use in this assay.

- a. To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril.

2. Nasopharyngeal Swab:

Use sterile rayon, foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal sample.

- a. To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Pass the swab directly backwards without tipping the

Policy Title	Influenza A & B	Policy #	LAB131031
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swab head up or down. The nasal passage runs parallel to the floor, not parallel to the bridge of the nose. Using gentle rotation, insert the swab into the anterior nare parallel to the palate advancing the swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. DO NOT USE FORCE while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.

Direct nasal or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal or nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct nasal or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection.

*** Note: Minimal dilution of the sample is recommended as dilution may result in decreased test sensitivity.*

VII. QUALITY CONTROL

ID NOW Influenza A & B 2 has built-in procedural controls. The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting Review Memory on the instrument.

Procedural Controls:

ID NOW Influenza A & B 2 contains an internal control that has been designed to control for sample inhibition, amplification and assay reagent function. In positive samples where target amplification is strong, the internal control is ignored and the target amplification serves as the 'control' to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust. At a very low frequency, clinical samples can contain inhibitors that may generate invalid results.

Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

External Positive and Negative Controls:

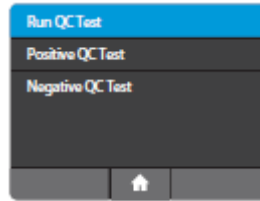
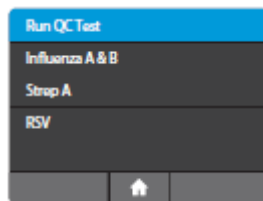
Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW Influenza A & B 2 kits contain Positive and Negative Control Swabs. These swabs will monitor the entire assay. Test these swabs once with each time a new box is opened or a new shipment is received and once for each untrained operator.

External Positive and Negative Control swabs are provided and should be tested following the Run QC Test instructions on the ID NOW Instrument.

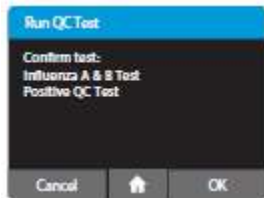
Quality Control Swab Test Procedure

1. For QC testing, select Run QC Test on the Home screen, and follow the displayed instructions. Select Influenza A & B; select the test to be run.

Policy Title	Influenza A & B	Policy #	LAB131031
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2. Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.



Note: The QC test is run in the same manner as a Direct Nasal/Nasopharyngeal Swab Patient Test. Refer to Procedure beginning at step 4 "Loading the Components" for further instruction.

***Note: The ID NOW Instrument reports QC results as Pass or Fail. Flu A/B Positive QC pass indicates a positive result for both influenza A and influenza B.*

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

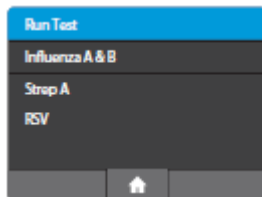
VIII. PROCEDURE

Before testing with ID NOW Influenza A & B 2 allow all samples to reach room temperature.

1. Touch screen to wake up instrument.
 - a. Enter UserID and Password



2. Select Run Test; select Influenza A & B



Policy Title	Influenza A & B	Policy #	LAB131031
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3. Enter specimen accession number



4. Load the components

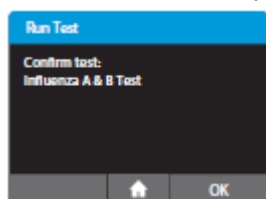
Orange Test Base:

- a. Open the Lid and Insert Orange Test Base into Orange Test Base holder



CAUTION: Do not apply excessive force. Excessive force could damage the instrument.

Confirm that the correct test is displayed on the screen.



- b. Touch 'OK' to proceed.

CAUTION: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded. If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a self-test before proceeding to the Home screen. Press Run Test and restart the test using the correct Test Base.

Blue Sample Receiver:

- c. Insert Blue Sample Receiver into the Blue Sample Receiver Holder

CAUTION: Do not apply excessive force. Excessive force could damage the instrument.



CAUTION: Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test. If the test is not started within 10 minutes, the instrument will time out and all test

Policy Title	Influenza A & B	Policy #	LAB131031
---------------------	-----------------	-----------------	-----------

pieces (Test Base and Sample Receiver) must be removed and discarded. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.

- d. Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once Warm Up begins.



CAUTION: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.

DO NOT close the lid or insert the sample until prompted by the instrument.

- e. When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.



- f. Vigorously mix the swab in the liquid for 10 seconds. Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab.
- g. Once the swab is removed, touch 'OK' to proceed.

CAUTION: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.

White Transfer Cartridge

- h. Press the White Transfer Cartridge into the Blue Sample Receiver. Listen for a click.

When the transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.

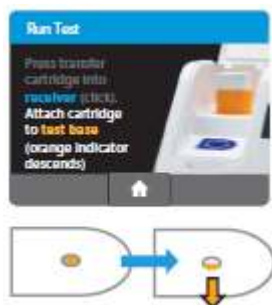
Policy Title	Influenza A & B	Policy #	LAB131031
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CAUTION: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.

- i. Lift and then connect the Transfer Cartridge to the Test Base.

When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.



CAUTION: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false negative results.

- j. Close the Lid when prompted. The lid must be closed with 30 seconds or the test will be aborted.

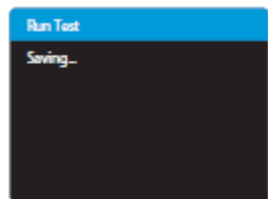


CAUTION: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument will proceed to the Home screen. Collect a new sample from the patient. Press Run Test and restart the test using a new Test Base and Sample Receiver.

CAUTION: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.

Policy Title	Influenza A & B	Policy #	LAB131031
---------------------	-----------------	-----------------	-----------

5. When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen. The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.



The Test Results screen displays either a Negative or Positive result for a successfully completed test. If a test error occurs, the display will read 'Invalid'. Refer to the Result Interpretation Section for Interpretation of Results.

6. Press Print to print test results, press New Test to run another test, Press Home to return to the Home screen.

After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces. Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and clicking it into the Sample Receiver, by pressing into the Sample Receiver.



7. Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.



8. Place print out on Result Log.

If an Invalid result is received, one additional test may be run using the same Sample Receiver. The instructions below should be followed:

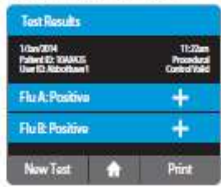



- Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. The connected Test Base and Transfer Cartridge MUST be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package may be used for this.
- Remove the blue Sample Receiver separately and carefully from the instrument. The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents.

Policy Title	Influenza A & B	Policy #	LAB131031
---------------------	-----------------	-----------------	-----------

- From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and DO NOT re-elute the swab.
- If repeat testing result is valid, report result. If repeat testing result is invalid, obtain new specimen.

IX. INTERPRETATION

When the test is complete, the results are clearly displayed on the instrument screen. An individual result for both influenza A and influenza B will be provided.

Instrument Display	Interpretation of Results and Follow-up Actions
 <p>The screenshot shows the 'Test Results' screen with the following information: Date/Time: 1/06/2014 11:22am, Patient ID: 304435, User ID: Administrator. Results: Flu A: Positive, Flu B: Positive. Buttons: New Test, Home, Print.</p>	<p>Flu A Viral RNA Detected; Flu B Viral RNA Detected.</p> <p>Dual infections of Flu A and Flu B are rare. Repeat testing using new test components. Contact Technical Support during normal business hours if multiple samples provide this result.</p> <p>This result does not rule out co-infections with other pathogens or identify any specific influenza A or influenza B virus lineage.</p>
 <p>The screenshot shows the 'Test Results' screen with the following information: Date/Time: 1/06/2014 11:22am, Patient ID: 304435, User ID: Administrator. Results: Flu A: Negative, Flu B: Negative. Buttons: New Test, Home, Print.</p>	<p>Flu A Viral RNA Not Detected; Flu B Viral RNA Not Detected.</p>
 <p>The screenshot shows the 'Test Results' screen with the following information: Date/Time: 1/06/2014 11:22am, Patient ID: 304435, User ID: Administrator. Results: Flu A: Invalid, Flu B: Invalid. Buttons: New Test, Home, Print.</p>	<p>The presence or absence of Flu A and Flu B Viral RNAs cannot be determined.</p> <p>Repeat testing of the sample using new test components. If repeated Flu A and Flu B Invalid results are obtained, results should be confirmed by another method prior to reporting the results.</p>
 <p>The screenshot shows the 'Test Results' screen with the following information: Date/Time: 1/06/2014 11:22am, Patient ID: 304435, User ID: Administrator. Results: Flu A: Negative, Flu B: Positive. Buttons: New Test, Home, Print.</p>	

X. LIMITATIONS

- The performance of the ID NOW Influenza A & B 2 was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- ID NOW Influenza A & B 2 performance depends on viral RNA load and may not correlate with cell culture performed on the same specimen. Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply the corresponding virus(es) are infectious, or are the causative agents for clinical symptoms.
- Performance of ID NOW Influenza A & B 2 has not been established for monitoring antiviral treatment of influenza.
- Although this test has been shown to detect A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for the

Policy Title	Influenza A & B	Policy #	LAB131031
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A/H1N1 (pre-2009 pandemic), A/H7N9 (detected in China in 2013) and A/H3N2v viruses have not been established.

- There is a risk of false negative results due to the presence of sequence variants in the viral targets of the assay. If the virus mutates in the target regions, influenza viruses A or B may not be detected or may be detected less efficiently. Additionally, if the sequence variant occurs in the target sequence recognized by the fluorescently-labeled molecular beacon an invalid assay may result.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may occur if inadequate levels of viruses are present in the specimen.
- False negative results may occur if mucin concentrations of 1% (w/v) or greater are present in the specimen.
- False negative results may occur if Respiratory Syncytial Virus is present as a co-infecting organism.
- Potential interference effects from FluMist™ have not been evaluated. Individuals who have received nasally administered influenza vaccine may test positive in commercially available influenza rapid diagnostic tests for up to three days after vaccination.
- This test is not intended to differentiate Influenza A subtypes or Influenza B lineages. If differentiation of specific influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Negative results do not preclude infection with influenza virus and should not be the sole basis of a patient treatment decision.
- Positive and negative predictive values are highly dependent on prevalence. The assay performance was established during the 2016 to 2017 influenza seasons. The positive and negative predictive values may vary depending on the prevalence and population tested.
- This test has not been evaluated for patients without signs and symptoms of influenza infection.
- The test is a qualitative test and does not provide the quantitative value of detected organism present.
- Cross-reactivity with respiratory tract organisms other than those tested in the Analytical Specificity Study may lead to erroneous results.
- This assay has not been evaluated for immunocompromised individuals.
- This test cannot rule out diseases caused by other bacterial or viral pathogens. The regions selected for amplification are conserved among all known Influenza A and Influenza B subtypes and strains (where sequence data is available from public databases). Laboratory testing has shown that ID NOW Influenza A & B 2 can readily amplify and detect H1N1 (pre-2009 pandemic), H3N2 (variant) and H7N9 (detected in China in 2013) influenza subtypes but the performance of the assay for detection of these subtypes in a clinical setting has not been established due to the lack of clinical samples.

XI. REPORTING RESULTS

Record result in MedHost HMS as Positive or Negative under the Rapid Influenza Screen test.

XII. ATTACHMENTS

1. ID NOW Result and QC Form
2. ID NOW New Lot Log

XIII. REFERENCES

Policy Title	Influenza A & B	Policy #	LAB131031
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1. ALERE™ i Influenza A & B 2 Product Insert IN427000 Rev. 4 2018/04

Policy Title	Medical Necessity and ABN Form Use	Policy #	LAB1823
Responsible	Laboratory Director	Revised/Reviewed	09/2020 10/31/2022

I. PURPOSE

The ABN allows the beneficiary to make an informed decision about whether to get the item or service that may not be covered and accept financial responsibility if Medicare does not pay. If the beneficiary does not get written notice when it is required, he or she may not be held financially liable if Medicare denies payment, and the hospital may be financially liable if Medicare does not pay.

II. POLICY

An Advance Beneficiary Notice must be obtained when one or more of the following circumstances exist when WCH wishes to bill the patient for the provided services:

1. Medicare does not cover the test for a routine or screening examination.
2. The test is for investigative or research use only.
3. The diagnosis provided may not or does not meet medical necessity requirements.
4. No diagnosis provided.
5. The test may only be paid for a limited number of times within a specified period of time and the visit may exceed that limit.
6. The Food and Drug Administration has not approved the test.
7. For those services which Medicare excludes from coverage under Part A or Part B (e.g., tests associated with routine checkups, glasses, hearing aids, routine foot care, personal

An acceptable ABN must meet the following criteria:

- The ABN notice must be given in writing, prior to testing or procedures provided.
- The ABN notice must include the patient's name, date, description of test/procedure, the estimated costs of these services, the reason(s) each test/procedure may not be covered by Medicare and the patient's final decision on how to proceed after the ABN notice has been explained.
- The patient must be asked to sign and date the ABN each time an ABN is required, indicating that he or she accepts financial responsibility for payment of the services provided should Medicare deny
-

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Check patient requisition for a diagnosis code or written symptoms. If none appears or if the order is not signed, it is not a valid order and one must be obtained from the physician's office. Follow procedure for obtaining valid orders.
2. Order tests in the HMS computer and the given diagnosis.
3. The Medical Necessity component of the computer software will flag any tests not covered by the given diagnosis.

Policy Title	Medical Necessity and ABN Form Use	Policy #	LAB1823
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4. Determine if an ABN is indicated.
5. Using the script contained in the "HCFA Medicare Update Notebook" as a guide, explain to the patient that Medicare or other third party payor may not pay for the test.
6. Give the patient the choice of whether or not they want the test(s) and that may be liable for payment.
7. Depending on the patient's choice, follow the instructions given in the HCFA notebook and complete the ABN Form.
8. Have the patient sign the form (English or Spanish as appropriate). Give them a copy. Submit a copy to HIM and to the Business Office.
9. Refer to lab management in the event the patient is still unsure of the ABN and its significance.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Clarification of Physician's Orders or Diagnosis Codes	Policy #	LAB1827
Responsible	Director of Laboratory	Revised/Reviewed	10/23/2020 10/31/2022

I. PURPOSE

Communication with a physician or their office staff is essential to resolve order or diagnosis code clarification issues.

II. POLICY

When the laboratory staff is unable to interpret a physician's orders for laboratory testing, the laboratory will contact the physician's office to receive clarification on what testing is desired.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. When a technician is unfamiliar with the test ordered, or orders or diagnosis information is inadequate or unclear, a laboratory staff member will make a telephone call to the physician for clarification.
2. If the laboratory staff is unable to reach the physician, the patient should be requested to wait until the office is contacted or to return after resolution of the issue. The laboratory will telephone the patient to return once the physician's orders have been clarified.
3. In the interest of customer satisfaction, order clarification must be handled in the most expedient manner possible. Care must be taken to communicate with the patient in a manner that alleviates undue concern.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Competency Assessment of Testing	Policy #	LAB1828
Responsible	Laboratory Director	Revised/Reviewed	<u>10/17/2022</u> 11/2020

I. PURPOSE

To lay a firm foundation for competency assessment and implement an ongoing and interactive verification of knowledge and skills, while promoting a culture of safety. The goal is to provide high quality patient care through skilled, competent personnel whose competency is validated and maintained via a structured program.

II. POLICY

- Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have training and be evaluated for proper test performance as required.
- Retraining and reassessment of employee competency must occur when problems are identified with employee performance

• For waived testing:

Competency assessment must be performed at least annually (semiannual assessment not required).

• For nonwaived testing:

- During the first year of an individual's duties, competency must be assessed at least semiannually.
- After an individual has performed his/her duties for one year, competency must be assessed at least annually.
- Competency assessment must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system.
- Assessment will follow the CLIA required guidelines that define how and by whom competency must be assessed based on the complexity of that test or test system.
- Competency assessment is required on all testing personnel, including Point of Care and contract staff. Competency assessment is separate and distinct from the Orientation process, although there may be some overlap with the Laboratory Orientation program.
- Prior to performing laboratory testing without supervision, the Laboratory Medical Director documents completed competency assessment for all assigned tests and the staff member affirms this in writing.

III. PROCESS

IV. DEFINITIONS

Competency- is the demonstrated ability to fulfill the primary responsibilities of the position for which a person was hired.

Policy Title	Competency Assessment of Testing	Policy #	LAB1828
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Test System- the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel, or single use and can include reagents, components, equipment, or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

V. PROCEDURE

- A. These six methods will be used to assess competency for all moderate and high complexity testing (if applicable to the test or test system) and verification documentation will be maintained.
 1. Direct observations of routine patient test performance,
 2. Monitoring, recording and reporting of test results,
 3. Review of test results, worksheets, quality control, proficiency testing, and preventive maintenance.
 4. Direct observation of instrument maintenance function checks, calibrations, calibration verifications, and correlations.
 5. Test performance by PT, blind samples, or retesting samples previously analyzed.
 6. Problem solving skills appropriate to the job/test.
- B. Competency evaluation is an ongoing process. Each staff member must have a competency file to keep documentation supporting completion of the required elements. Date and initials of the preceptor performing the assessment or observation should accompany each document.
- C. Each task/platform must be independently evaluated using the six methods listed above if applicable. Assessment cannot be performed in one day for multiple departments and tests.
- D. Waived tests and methods must have competency evaluated using two of the methods listed below and documentation maintained.
 1. Direct observation
 2. Written test
 3. Proficiency testing or blind samples
 4. Review of performance of quality control.
- E. Many of the elements of competency assessment are performed during routine review of an employee throughout the year. Records of these elements, including adherence to laboratory policies and procedures, observation of test performance, results reporting, instrument maintenance, review of worksheets, recording QC, performance of PT, and demonstration of taking appropriate corrective actions are examples of daily activities that can be used to demonstrate competency. If elements of competency are assessed by routine review, the competency procedure must outline how this routine review is used to evaluate competency. Competency assessment during routine review may be recorded using a checklist.
- F. The medical director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing.
 1. The section lead/Technical supervisor, or a testing personnel meeting a technical supervisor requirements for high complexity testing if delegated in writing by the medical director shall assess testing personnel performing high complexity testing.
 2. Testing personnel performing moderate complexity testing, must be assessed by an individual meeting the qualifications of a technical consultant/supervisor for moderate complexity, as defined by CLIA.
- G. Completed competency assessment forms are reviewed by the Laboratory Medical Director and signed. This signature attests that the staff may perform all tests they have been deemed competent to do.

Policy Title	Competency Assessment of Testing	Policy #	LAB1828
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H. Performance Assessment of Technical Supervisors/Consultants/Leads

The laboratory medical director must delegate in writing all responsibilities of the medical director (as technical supervisors in laboratories performing high complexity testing) and technical consultants (in laboratories performing moderate complexity testing, but not high complexity testing). Unsatisfactory performance must be addressed in a corrective action plan.

I. REASSESSMENT OF COMPETENCY

Develop a correction action plan if an employee fails to demonstrate satisfactory performance on the competency assessment. If, after re-education and training, the employee is unable to satisfactorily pass the assessment, then further action should be taken which may include, supervisory review of work, reassignment of duties, or other actions deemed appropriate by the laboratory director.

J. DOCUMENTATION:

Competency assessment documentation must be maintained and include:

- Complete signed competency forms
- Competency files with supporting documentation

K. References and Citations:

- CLIA Clinical Laboratory Personnel Requirements;
- The Joint Commission Comprehensive Accreditation Manual – Laboratory; Competency Assessment Policy Attachment A Final Competencies Workbook

VI. REFERENCES

N/A

VII. STAKEHOLDERS

N/A

Policy Title	Confirmation of Verbal Orders	Policy #	LAB1829
Responsible	VP Ancillary Services	Revised/Reviewed	11/2020 10/17/2022

I. PURPOSE

To document and confirm all tests requested and restrict test requisitions to authorized individuals.

II. POLICY

The laboratory must perform tests only on the written or electronic request of authorized persons. Oral requests are permitted only if the laboratory subsequently obtains written or electronic authorization for testing within 30 days and retains the written authorization, or documentation of its attempts to obtain written authorization.

III. DEFINITIONS

N/A

IV. PROCEDURE

Physicians will be encouraged to provide their patients with written orders for tests or to send an order to the laboratory via fax. When obtaining an order by telephone, the laboratory technician or technologist will complete patient information portion of the Confirmation of Verbal Orders Request, including requested test, patient's name, diagnosis and birth date. Verbal orders must be followed up with a read back to ensure correct information has been obtained. The request must then be faxed to the physician's office. When the request is returned, it will be filed with other laboratory and registration information.

V. REFERENCES

The Joint Commission Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, current edition

VI. STAKEHOLDERS

N/A

Policy Title	Correction and Reporting of Laboratory Errors	Policy #	LAB1830
Responsible	Laboratory Director	Revised/Reviewed	11/2020 10/31/2022

I. PURPOSE

To establish a reporting mechanism for quality issues
 To identify opportunities for quality improvement projects
 To standardize incident reporting
 To provide an audit trail of test correction activities

II. POLICY

Laboratory errors, and errors originating outside the Laboratory will be reported using the Hospital's Risk Identification Report form. The Risk Identification Report form is a confidential form used for quality improvement and documentation purposes. All errors detected in the laboratory will be corrected and documented using this standard protocol. This policy is not intended to be punitive in nature. It is followed to help ensure the best possible Laboratory service is provided our community. Our purpose is to provide a measurement of performance and to identify areas of our laboratory practice that can be improved.

III. DEFINITIONS

N/A

IV. PROCEDURE

Risk Identification Report form.

- A. Complete the patient information (name, location, DOB, identification numbers, date and times) on the front of the form.
- B. Complete Section VIII and describe the incident, parties involved and resolution. Copies of reports, labels, orders etc. can be stapled to the Risk Identification Report.
- C. Indicate names of parties involved. Write your name as witness or reporting individual. This will help in the investigation.
- D. Submit to the Laboratory Director. If information within the report is sensitive, submit in a sealed envelope.
- E. The Laboratory Director will investigate, identify the Operational Phase of the incident (Request generation, Specimen Procurement and Handling, Testing, Reporting, Post report, Other) and the Incident Type (Clerical, Labeling, Safety, Result Validity, Education, Delay, Missing/Lost, Technical, Appropriateness, Identification, Verbal Communication, Specimen Quality, Other).
- F. The Laboratory Director will initiate and document appropriate corrective action. Information of a general or statistical nature about resolution of reported incidents may be shared with staff at Laboratory Meetings.
- G. Procedure - Correction of results after verification:
 1. The CLS will print a copy of the incorrect report
 2. The CLS will amend the test results in the LIS.
 3. The CLS will print a copy of the corrected report. A copy of both reports will be attached to the Risk Identification Report and submitted to the Laboratory Director.

Policy Title	Correction and Reporting of Laboratory Errors	Policy #	LAB1830
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4. INPATIENT- The CLS will verbally inform the patient's nurse. Ask the nurse to inform the physician if necessary. Document this contact including name of person to whom you spoke, in the call screen.
5. OUTPATIENT
 - a. The CLS will verbally inform the office supervisor or nurse of the amended result. Document this contact in the call screen.
 - b. FAX the corrected report or give it to the courier.
 - c. If the courier delivers the report to the physician's office, they will notify the office staff that they are delivering an amended report.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Laboratory Instrument Maintenance	Policy #	LAB1836
Responsible	Laboratory Director	Revised/Reviewed	09/01/2020 10/17/2022

I. PURPOSE

1. To ensure accuracy and precision of patient testing
2. To ensure timely reporting of results
3. To ensure that manufacturer's requirements for maintenance are followed
4. To prolong the life of instrumentation
5. To ensure that calibration verification and correlation studies of selected laboratory instrument are performed at a required time interval.

II. POLICY

In order to provide accurate, precise and timely patient results, preventive maintenance of laboratory instrumentation must be provided on a routine and on-going basis. All maintenance will be performed according to the manufacturer's suggestions except when experience dictates more frequent preventive maintenance. Maintenance responsibilities will be established by the laboratory and shared between laboratory personnel, Biomedical Engineering Department, the Engineering Department and purchased external services. In most instances, the laboratory will provide daily, weekly and quarterly maintenance requiring few mechanical skills and tools. Biomedical will provide more skilled servicing or maintenance, which requires the use of specialized tools. Maintenance activities will be logged by the servicing individual. This information should be available to any accrediting agency upon request.

III. DEFINITIONS

N/A

IV. PROCEDURE

Maintenance information should be reviewed monthly by the Section Head. In the event that maintenance has not been completed by Biomedical Engineering or contract services, the attached form letter regarding the deficiency should be sent to the appropriate parties. A copy of the letter should be kept for audit or future reference. In the event that equipment malfunction impacts the operation of essential pieces of equipment, the laboratory staff will attempt to resolve the problem. For problems that are outside the ability of the staff to remedy, staff will contact Biomedical Engineering or the vendor for additional support. Each piece of equipment that is damaged or inoperable will be immediately labeled with the red Medical Equipment Repair Request tag to avoid possibility of injury to operators.

Section: Hematology

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
STAGO Start 4 & Compact	Contract Service	annual
Beckman-Coulter HMX & LH500	Contract Service	annual
Microscopes manufacturer's p.m.	Contract Service	biannual
Hema-tech Stainer manufacturer's p.m.	Biomedical Engineering	annual
Refrigerated Centrifuge		

Policy Title	Laboratory Instrument Maintenance	Policy #	LAB1836
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manufacturer's p.m. Jordon Refrigerator	Biomedical Engineering	annual
manufacturer's p.m. Jewett Refrigerator	Engineering	annual
(under counter) Rotator	Engineering	annual
Multitimer	Biomedical Engineering	annual

Section: Pathology

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Tissue Processor manufacturer's p.m.	Contract services	Not in Use 1/1/2010
Cryostat		
manufacturer's p.m.	Biomedical Engineering	annual
minor maintenance	Biomedical Engineering	annual
Microscopes		
manufacturer's p.m.	Contract Services	annual
Dictaphones	Contract Services	as needed
Tissue Tek Embedding Center	Biomedical Engineering	Not in Use 1/1/2010
Leitz Microtome	Biomedical Engineering	Not in Use 1/1/2010
Oven/incubator	Biomedical Engineering	Not in Use 1/1/2010
Microwave	Biomedical Engineering	Not in Use 1/1/2010
Water Bath	Biomedical Engineering	Not in Use
Refrigerator (Kenmore)	Biomedical Engineering	annual

Section: Urinalysis

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Beckman Coulter	Hematology Staff	annual
Criterion	Biomedical Engineering	annual
Clay Adams Centrifuge	Biomedical Engineering	annual

Section: General Laboratory

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Eye Washes/Showers	Engineering	Month

Section: Microbiology

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Beckman Centrifuge		
manufacturer's p.m.	Biomedical Engineering	annual
Cytospin Centrifuge		
manufacturer's p.m.	Biomedical Engineering	annual
Laminar Flow Hood		
manufacturer's p.m.	Contract Service	annual
Fume Hood		

Policy Title	Laboratory Instrument Maintenance	Policy #	LAB1836
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as needed	Contract Service	as needed
Microscopes	Contract Service	annual
Anaerobic Chamber		
manufacturer's p.m.	Biomedical Engineering	annual
Incubators (4)		
manufacturer's p.m.	Biomedical Engineering	annual
Hot Plate		
calibration/		
manufacturer's p.m.	Biomedical Engineering	annual
Vortex Mixer		
manufacturer's p.m.	Biomedical Engineering	annual
BacT/Alert		
manufacturer's p.m.	Contract Service	annual
Refrigerators (3)		
manufacturer's p.m.	Engineering	annual
Heat Blocks (3)		
manufacturer's p.m.	Biomedical Engineering	annual
Bac-T incinerators (5)		
manufacturer's p.m.	Biomedical Engineering	annual
Vitek		
manufacturer's p.m.	Contract Service	annual

Section: Chemistry

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Beckman Coulter	Contract Service	annual
Access II		
Beckman Coulter DX (2)		
manufacturer's p.m.	Contract Service	annual
IEC Centrifuge		
manufacturer's p.m.	Biomedical Engineering	annual
Bayer Rapid Points		
manufacturer's p.m.	Contract Service	annual
Isotemp Refrigerators (2)		
manufacturer's p.m.	Engineering	annual
Kenmore Refrigerators		
manufacturer's p.m.	Engineering	annual
GE Refrigerator		
manufacturer's p.m.	Engineering	annual
Pipettes		
calibration/p.m.	Contract Service (adjustable)	annual
calibration/p.m.	Lab Staff (non-adjustable)	annual

Section: Transfusion Service

<u>Instrument/Task</u>	<u>Maintenance Assigned to</u>	<u>Interval</u>
Jordan Refrigerator		
clean interior and exterior	Transfusion Service staff	annual
door gasket oiled/cleaned	Biomedical Engineering	annual
vacuum condenser	Biomedical Engineering	annual
alarm system check	Biomedical Engineering	quarterly

Policy Title	Laboratory Instrument Maintenance	Policy #	LAB1836
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Preventive Maintenance	Engineering	annual
Blood Warmers		
manufacturer's p.m./		
temperature check	Biomedical Engineering	quarterly
Immufuge (2)		
lubricate "O" rings/latches	Biomedical Engineering	annual
check locking screws	Biomedical Engineering	annual
timer	Transfusion Service staff	quarterly
calibration	Transfusion Service staff	annual
Preventive	Maintenance Engineering	annual
RPM	Biomedical Engineering	annual
defrost/clean	Transfusion Services staff	annual
alarm system check	Biomedical Engineering	quarterly
RPR Rotator		
Preventive Maintenance	Biomedical Engineering	annual
Fisher Freezer		
clean interior/exterior	Transfusion Services staff	annual
Preventive Maintenance	Engineering	annual
Chart Movement PM	Biomedical Engineering	annual
defrost/clean	Transfusion Services staff	annual
alarm system check	Transfusion Services staff	quarterly
Helmer Platelet Incubator		
Preventive Maintenance	Biomedical Engineering	annual
Chart Movement PM	Biomedical Engineering	annual
defrost/clean	Transfusion Services staff	annual
alarm system check	Transfusion Services staff	quarterly
Immucor Spintek Centrifuge Washer		
Preventive Maintenance	Biomedical Engineering	annual
RPM	Biomedical Engineering	annual
Timer	Transfusion Services staff	quarterly
Calibration	Transfusion Services staff	annual
Washing Efficiency	Transfusion Services staff	annual
Immucor Automated Washer		
Preventive Maintenance.	Biomedical Engineering	annual
change tubing	Transfusion Service staff	quarterly
functional check	Transfusion Service staff	annual
Microscope		
manufacturer's p.m.	Contract Service	annual
Plasma Thawing Bath		
drain/clean/	Transfusion Service staff	quarterly
manufacturer's p.m.	Biomedical Engineering	annual
Ohaus Scale		
calibration/		
manufacturer's p.m.	Biomedical Engineering	annual

CALIBRATION VERIFICATION AND CORRELATION STUDY

1. Calibration verification of the following instruments are required every 6 months;
Chemistry : Beckman Coulter DXC, Rapid Point 405 & Beckman Coulter Access
Hematology: Beckman Coulter LH 500 & HMX

Policy Title	Laboratory Instrument Maintenance	Policy #	LAB1836
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Cath LaB : AVOX

2. Calibration verification is performed whenever the following events occur;
 - Major preventive maintenance is performed or critical parts are replaced that may influence test performance.
 - Quality control results indicate that there may a problem with the test system or unusual trend or shift.
 - An environmental change including instrument relocation
 - Instrument replacement
3. Correlation studies to evaluate the results of the same test performed with different methodologies or instrument must be performed every six months.
 Chemistry : Beckman Coulter DXC, Rapid Point 405 & Beckman Coulter Access
 Hematology: Beckman Coulter LH 500 & HMX

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Method Validation Prior to Implementation	Policy #	LAB1840
Responsible	Laboratory Director/ Manager	Revised/Reviewed	01/21/10 10/31/2022 <u>2</u>

I. PURPOSE

To ensure that a new procedure, reagent or instrument performs at an acceptable level.

II. POLICY

The following procedures will be followed to verify test accuracy when introducing new methods, instruments, or reagents.

III. DEFINITIONS

N/A

IV. PROCEDURE

Equipment or reagents as needed

Procedure for a New Instrument

- A. With the manufacturer's assistance, the instrument will be set up, linearity verified, calibrated and a "ready" state established.
- B. Precision will be determined by multiple runs of known material and CV's will be calculated (when applicable).
- C. Generally, 20 patient specimens will be run on the new instrument.
 1. Correlation between the existing method and the new method will involve data analysis (or linear regression studies) for:
 - a. Correlation coefficient
 - b. Slope
 - c. Intercept
 - d. Bias

Procedure for new reagent/method

- A. See IIIc above.

Data Review

- A. Data will be submitted to the Director for preliminary review.
- B. Final review and acceptance of data by the Medical Director prior to implementation must be completed.

Implementation Requires the Following:

- A. For a New Instrument:
 1. Manufacturer's set-up of instrument.
 2. Training of key operators.
 3. Acceptable correlation and performance studies signed off by the Medical Director.
 4. A written policy and procedure for all operators to read.
 5. Established test name, and normal ranges input into the LIS.

Policy Title	Method Validation Prior to Implementation	Policy #	LAB1840
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- 6. Assigned service code input into HIS.
- 7. Training of order entry personnel when needed.
- B. For a New Method:
Follow steps VI A 2-5, above.

Post Implementation

- A. For a New Instrument:
The instrument will be monitored by the Section Head for the first 6 months and assessed for efficiency, reliability and accuracy. Every effort will be made to work with the manufacturer to achieve success.
- B. For a New Method or Reagent:
Performance will be monitored by the Section Head for several months to ensure proper performance.

V. REFERENCES
N/A

VI. ATTACHMENT
ONE

VII. STAKEHOLDERS
N/A

Policy Title	Method Validation Prior to Implementation	Policy #	LAB1840
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Test/Instrumentation Validation Checklist

1. Do you need an interface? Yes/No
If yes, please initiate the process by sending an email to the IT dept/ WCH- LIS account manager.
2. Are there any new test/methods involved?
Yes/No
If yes, is the LIS person aware of the new test? Yes/No
3. Are there old tests to deactivate? Yes/No
If yes, is the LIS person aware of the old tests? Yes/No
4. Has the CDM been created for your new tests so we can get paid? Yes/No
What is the CPT code(s), charge code, revenue code, pricing and description?
5. Has this new item been tested in the test environment? Yes/No
6. Have all the reference ranges been checked for accuracy?
7. Does the WCH laboratory critical values need to be updated?
8. Are all appropriate Canned Comments built for the new test/method?
Any issues?
9. Has QC been tested in the test environment? Yes/No
Any issue? Yes/No
10. Has your validation been signed off with a cover sheet by the pathologist?
Yes/No
Is everything Complete? Yes/No
11. Are your policies either updated or have new policies been created? Yes/No
12. Have the old policies been removed?
NOTE: Please discard the retired SOP after 2 years.
13. Have these policies been signed by the pathologists?
Yes/No

Policy Title	Method Validation Prior to Implementation	Policy #	LAB1840
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14. Has the electronic version of the new policies been submitted to the management team to be uploaded in MCN?

15. Have you picked a go live date? Yes/No

16. Are all involved/impacted parties aware of what this date is? Yes/No

Test/Instrumentation Validation Checklist

17. What is the go live date?

18. Do we need to send a memo to all WCH employees regarding the new test/method?

19. Do providers/ RNs need education? Yes/No

20. Are they aware of this need? Yes/No

21. Have you trained laboratory staff involved? Yes/No

22. Have you adjusted your inventory to reflect the new demand for supplies?
Yes/No

Are your items set up in Medhost/Purchasing? Yes/No

23. Are there any regulatory /CAP issues related to this change? Yes/No

24. Have you made the appropriate changes to comply with the regulations? Yes/No

25. Are you going to gather data for next few months to create an IQCP? Yes/No

26. Has the lab manager/director reviewed and signed off on your project? Yes/No

27. What is your plan as far as Monthly/yearly Maintenance, Preventive Maintenance?

<u>Policy Title</u>	<u>Pending Test Reports</u>	<u>Policy #</u>	<u>LAB1846</u>		
<u>Responsible</u>	<u>Laboratory Director</u>	<u>Revised/Reviewed</u>	<u>10/18/2022</u>		

Policy/Procedure Title	Pending Test Reports	Manual Location	Laboratory		
Policy/Procedure #	1846	Effective	2/05	Page	1 of 1
Department Generating Policy	Laboratory	Revised	01/16		
Heinrik Bui, MS, MLS(ASCP)cm, CLS		Dept/Title	Laboratory Admin Director		
Paula Quinn, MD		Dept/Title	Laboratory Medical Director		

I. PURPOSE

To ensure that tests ordered in the LIS are completed in a timely manner and to provide a mechanism for investigation of incomplete tests.

II. POLICY

Pending reports will be run and investigated by each clinical lab scientist prior to shift change.

III. DEFINITIONS

N/A

IV. PROCEDURE

- 45-minutes prior to shift change, print a pending list for each workstation in your assigned area. Follow department specific protocol as outlined in the departmental procedure manual.
- Investigate every specimen on the pending list. Highlight future timed draws.
- Check for specimens that have been received and locate the specimens. Indicate on the list where the specimens are: refrigerator, running, spinning, etc.
- Check for specimens that have not been received:
 - Check under specimen comments for explanations, (patient unable to void and will return with specimen this p.m.).
 - Check under order comments for identification as an add-on.
 - Check for results; if other results are there, the specimen is here somewhere!
 - Check ordering time; if more than 2 hours have elapsed since the time of order, check with the phlebotomists, floor and specimen processing as appropriate.
 - Check the list from the previous shift(s) for pertinent comments on specimen location.
- Every specimen on the list must be accounted for.
- After all specimens have been accounted for, sign off the list to the following shift, using initials and time. When possible, discuss the list with the on-coming CLS.
- On-coming shift will countersign.
- Pending lists will be saved for a minimum of 2 weeks in a location designated by the department section head. Check the department specific procedure manual for more information.

IV. REFERENCES

N/A

V. STAKEHOLDERS

	1 st	2 nd	3 rd	4 th	5 th
Reviewed Date:	12/12	01/16	1/19		
By:	C. Moore	M. Salem	HB		

Policy Title	Specimen Labeling, Receipt, Collection and Transportation	Policy #	LAB1851
Responsible	Laboratory Director/ Laboratory Operations Manager	Revised/Reviewed	11/2020,01/202 <u>10/31/2022</u>

I. PURPOSE

To ensure correctly collected and labeled specimens are received in the Laboratory. To ensure unacceptable specimens are not tested.

II. POLICY

The laboratory has a mechanism to document specimen collection, unacceptable specimen condition and receipt of the specimen by the lab.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Labeling:

LIS – The laboratory information system generates a label or series of labels for each order.

The computer-generated demographic portion of the label contain the following information:

1. Accession number (computer generated)
2. Patient's account number/ encounter number (generated by registration)
3. Date/Time of test ordered
4. Date to collect including priority of collection
5. Patient's name/age
6. Patient's date of birth (DOB)
7. Medical record number/physician
8. Patient location/department/specimen requirements
9. Bar code (if applicable)
10. Test(s) ordered

The computer-generated barcode portion of the label contain the following information:

11. Accession number (computer generated)
12. Patient's account number/ encounter number (generated by registration)
13. Patient's name
14. Patient's date of birth (DOB)
15. Physician's Name
16. Barcode (if applicable)
17. Test(s) ordered

Policy Title	Specimen Labeling, Receipt, Collection and Transportation	Policy #	LAB1851
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The phlebotomist will Re-checks patient's information and add:

1. Initials of phlebotomist
2. Date/time of draw

LIS Down-Time – In the event the LIS is unable to generate labels, the minimum requirements for labeling specimens (by lab or non-laboratory employees) are:

1. Patient name (Last, First)
2. Medical record number (assigned generic number generated by registration)
3. Date of birth (month/day/year)
4. Initials of phlebotomist
5. Date/time of collection

On all specimens that are identifiable but not meeting the minimum label requirements of the laboratory the following comment will be entered into the LIS by the receiving person, "specimen received incompletely labeled/unable to positively confirm specimen identity". Except for difficult to obtain specimens such as CSF or ABG all specimens received unlabeled or labeled in such a way as to be unidentifiable will be discarded. The specimen submitting entity will be notified and steps taken to obtain a new specimen will be taken when possible and if indicated.

A. Collection:

Laboratory employees will confirm their draws in the LIS. The phlebotomist's initials will then be part of the patient's permanent record for that specimen. Specimens drawn by other than Lab personnel will be recorded by the Lab person using RN (nurse), DO (drop off), LNE (line draw by RN) or, if available, the alphanumeric code of the person who has drawn the patient. The current date and time of collection is automatically entered by the LIS unless a specific date/ time is manually entered. It is very important that date and time entries are correct; automatic defaults are not acceptable. If the time of collection is not known call floor and notify source that the specimen must be labeled with collector initials and time of collection. Notify specimen collection entity to come to lab and label correctly or the specimen will be processed. It is not acceptable for the lab to complete the labeling process.

B. Transportation of Specimens:

Specimens will be transported to the laboratory using plastic zip-lock bags imprinted with the orange biohazard symbol. Specimens collected in an SST /Gold (serum separated tube or Red top tube should be transported in an upright position to assure specimen and test result integrity. submitted with needles attached or externally contaminated specimens will be subject to correction by Nursing personnel and a follow-up Quality Assurance report.

C. Receipt:

Phlebotomists will confirm in the LIS the receipt of specimens into the lab. The phlebotomist's initials will then be a part of the patient's permanent record for that specimen. Specimens drawn by other than Lab personnel will be received by a Laboratorian. The technician's initials will then be a part of the patient's permanent record for that specimen. Specimens that are picked up by the lab will be checked by the courier to verify proper labeling of specimen. If specimen labeling is not complete, the courier will notify the appropriate staff before taking the specimen. Drop Off specimens will be checked by lab personnel to verify appropriate labeling before specimen is allowed to be left on specimen processing tray. Lab personnel

Policy Title	Specimen Labeling, Receipt, Collection and Transportation	Policy #	LAB1851
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will confirm proper handling or special handling of all specimens brought to the lab to include, but not limited to, timely delivery of specimens, chemistry tubes delivered to the lab and centrifuged, if applicable, within two (2) hours of sample draw, received on ice/heat/protected from light as appropriate.

D. Relabeling:

In an event where a sample should be relabeled with a new add on test label, a minimum of two identifiers must be checked to accurately identify the patient. Patient's room or bed must not be used as a patient's identifiers. The label must be placed on the tube in a way that it does not cover the original label (two patient's identifier including patient's full name must not be covered). Any laboratory staff who make an attempt to relabel must write his/her initial on the added label.

E. Unusual or Significant Condition of Specimens:

All specimens received into the lab are assumed to have been collected under approved conditions and to meet the laboratory's requirements for volume, no hemolysis, etc. Clinical Laboratory Scientists, Phlebotomist/Laboratory Technicians must indicate any information regarding unusual or significant conditions of specimens that impact the acceptability of the specimens. This information will be entered into the LIS and will become a permanent part of the report.

II. REFERENCES

N/A

III. STAKEHOLDERS

N/A

Policy Title	Standing Orders	Policy #	LAB1853
Responsible	Laboratory Director	Revised/Reviewed	11/2020 10/31/2022

I. PURPOSE

To ensure the continuing validity of existing standing orders.

II. POLICY

Standing orders are used for patients with chronic conditions who require regular monitoring. The laboratory requires a renewal of standing orders from physicians every 6 months. The laboratory will review standing orders monthly to discover any expiring standing orders.

III. DEFINITIONS

N/A

IV. PROCEDURE

- A. Standing orders will be reviewed monthly to determine if any are nearing expiration.
- B. The Physician's office will be notified by the courier or by fax of any standing order whose original date is 5 months old or greater that a renewal order is necessary.
- C. When a new standing order is received the expiration date will be written on it, and it will be filed alphabetically in the Standing Order Binder in the front office.
- D. If the new requisition has not been received by the following month's review, the order becomes invalid.
- E. The expired standing order will be pulled from the standing order binder and discarded.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Thermometer Verification	Policy #	LAB1854
Responsible	Laboratory Director	Revised/Reviewed	12/2020 12/15/20 <u>22</u>

I. PURPOSE

To check all thermometers in use in the laboratory for accuracy against an NBS (National Bureau of Standards) certified thermometer prior to usage and annually, thereafter.

II. POLICY

N/A

III. DEFINITIONS

N/A

IV. PROCEDURE

EQUIPMENT:

1. NBS certified thermometer.
 2. Thermometer to be calibrated.
 3. Heated or cooled water at temperature thermometer will be required to monitor.
 4. Chart – see attached.
1. Assign the thermometer to be calibrated the next consecutive number on the calibration log.
 2. If the area the thermometer is required to monitor is between 1° and 95° C, a beaker of water should be placed in the refrigerator or incubator to equilibrate for at least 30 minutes prior to the test.
 3. Place the NBS thermometer and the thermometer to be calibrated in the water, freezer or oven in the same location and at the same time. Read the temperature after a minimum of 3 minutes.
 4. Record the temperature of both thermometers on the chart in the appropriate areas. Calculate and enter the deviation on the non-NBS thermometer from the calibrated NBS thermometer.
 5. If the deviation is less than 0.5° from the NBS thermometer, the thermometer may be placed in service. Fix a non-obstructive but permanent label to the top of the thermometer, indicating the deviation from expected. Note the deviation factor on quality control charts and recalculate the acceptable limits for incubators, freezers, refrigerators or room temperature.
 6. If a new thermometer deviates by >0.5°, it should be returned to purchasing as defective.
 7. Thermometers needing additional calibration or verification will be noted in individual procedure manuals.

NOTE: The laboratory will not use thermometers containing mercury.

V. REFERENCES

Technical Manual. American Association of Blood Banks, 14th Ed, 2002.

VI. STAKEHOLDERS

N/A

Policy Title	Proficiency Testing Program	Policy #	LAB1856
Responsible	Laboratory Director	Revised/Reviewed	09/2020 10/31/2022

I. PURPOSE

The laboratory will perform proficiency testing to assess the accuracy of test results, and to confirm to CLIA regulations.

II. POLICY

Proficiency testing material is supplied through vendors that have been approved through CLIA. The samples are tested in the same manner as patient testing, by a variety of staff members on a rotation basis. Remedial actions and a thorough investigation are taken when results are not within acceptable limits.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Principle:

To comply with federal regulations, testing of proficiency materials will be performed by licensed Clinical Laboratory Scientists in the same manner as patient samples.

B. Specimens

Specimens are mailed to the laboratory on a regular schedule. Section Heads (SH) are responsible for contacting the appropriate proficiency-testing agency if specimens have not been received as expected. Specimens should be reconstituted and mixed per instructions by the CLS performing the assay. Section head assigns survey kit to CLS routinely running the test.

C. Instruments

Testing must be performed on each instrument routinely used for testing and reporting results.

If more than one instrument is used for testing of a specific analyte, the testing can be rotated between instruments, or each instrument may have its own test kit. Proficiency testing is not required on instruments that are used as "back-ups".

D. Reagents

Reagents normally used for patient testing will be used for all proficiency testing.

E. Quality Control

Control materials will be run as they are with patient testing. Extra Quality Control runs are not required for proficiency testing and are inappropriate.

F. Procedure

1. PT specimens will be treated as normal patient specimens, and processed according to standard operating procedures for that specific analyte.
2. The test results will be ordered into the LIS by the testing personnel as the PT is received.

G. In the event that the Section Head is not available, the survey will be entered into HMS by the Section Head's bench replacement. Tests will appear on the next worksheet printed and

Policy Title	Proficiency Testing Program	Policy #	LAB1856
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should be done as any other patient appearing on the worksheet. If tests are normally batched (RPRs, Rubellas, etc.), all PT specimens will be batched and run by the assigned CLS. Results shall be entered into the LIS and verified per established protocol.

H. Calculations

Any calculations required for reporting patient results will be calculated by the CLS performing the assay.

I. Reporting Results

1. Clinical Laboratory Scientists performing PT testing will report the results of the test on a the survey report form or enter results online.
2. Clinical Laboratory Scientists performing PT will sign the attestation in the appropriate area of the original report form.
3. Section Heads or designee will be responsible for reviewing the photocopies for accuracy and completeness and transcribing the results to the original report form.
4. Section Heads or designees are also responsible for informing laboratory management or pathologists of any difficulty in completing PT.
5. For electronic submission, Section heads or designee will enter the results in the website, print a copy and let a second person review the data entered for accuracy prior to submission.

J. PT surveys require the lab director or designee's signature prior to online submission. In the event the medical director is unavailable, lab director is designated as signee on the forms.

K. Evaluation of Results

1. Section Head
 - a. Receives results through the mail.
 - b. Reviews results looking for omissions, unacceptable results, failures, biases, outliers, overall performance, and cumulative performance. If unacceptable – Section Head investigates. Testing may be suspended if score is <80% for general testing < 100% for blood bank.
2. Lab Director – reviews comments, adds further corrective action, if applicable.
3. Pathologist – performs final review.
 - a. If unsatisfactory, may request additional documentation from SH.
 - b. If satisfactory, signs and returns to Lab Director to be filed.

L. Storage

1. With the exception of whole blood, leftover survey material should be frozen and saved.
2. After PT results have been returned from the accrediting agency, the material may be used for other purposes.

V. **HANDLING UNSUCCESSFUL PROFICIENCY TESTING**

The laboratory complies with The Joint Commission's requirements addressing unsuccessful proficiency testing. Unsuccessful proficiency testing is defined as a failure to achieve satisfactory performance for two consecutive or two out of three consecutive testing events. The following are considered unsatisfactory proficiency testing events:

- Failure to attain a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (Rho) typing and compatibility testing
- Failure to attain a score of 100% for ABO group and D (Rho) typing and compatibility testing.
- Failure to return proficiency testing results to the proficiency-testing provider within the period specified by that provider.

Policy Title	Proficiency Testing Program	Policy #	LAB1856
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- Omission of results on the proficiency testing form.

- Failure to participate in a proficiency-testing event

1. If notified by The Joint Commission of an unsuccessful proficiency testing status, the laboratory submits a plan of action within 10 calendar days of notification.
2. The laboratory must cease testing if unsuccessful proficiency testing is documented and one of the following occurs:
 - a. The laboratory has failed to submit a written Plan of Action after two requests from The Joint Commission.
 - b. The Plan of Action has not been found acceptable by The Joint Commission after three opportunities to provide an acceptable plan.
 - c. The laboratory fails to achieve satisfactory performance on one of the next two consecutive proficiency-testing events.
 - d. The nature, scope, severity, and duration of the underlying issue warrant a cease in testing, such as none consequential, but repeated, unsuccessful proficiency testing events.

Note: The laboratory must cease testing for at least six months after the notice is issued for the testing specified. The laboratory may not resume testing until the criteria for reinstatement are met and the laboratory receives written confirmation from The Joint Commission that it may resume testing.

VI. PT INTEGRATION ROUTINE WORKLOAD

1. The laboratory integrates all proficiency testing samples within the routine laboratory workload, and those samples are analyzed by personnel who routinely test patient/client samples, using the same primary method systems as for patient/client/donor samples

NOTE: Duplicate analysis of any proficiency sample is acceptable only if patient/client specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; etc.), group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample. If the laboratory uses multiple methods for an analyte, proficiency samples should be analyzed by the primary method. The educational purposes of proficiency testing are best served by a rotation that allows all testing personnel to be involved in the proficiency-testing program. Proficiency testing records must be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals.

VII. PT INTERLABORATORY COMMUNICATION AND PT REFERRAL

Interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency-testing provider is prohibited. The laboratory director is responsible for enforcing this prohibition. Referral of proficiency testing specimens to another laboratory is also prohibited. This prohibition takes precedence over the requirement that proficiency-testing specimens be handled in the same manner as patient specimens. For example, a laboratory's routine procedure for review of abnormal blood smears might be referral of the smear to a pathologist located at

Policy Title	Proficiency Testing Program	Policy #	LAB1856
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another site. For proficiency testing specimens, the referring laboratory must NOT follow its routine procedure in this situation. Rather, the laboratory must submit a PT result indicating that the test is not performed since the review does not occur within the referring laboratory.

VIII. REFERENCES

Department of Health And Human Services, Centers For Medicare & Medicaid Services.
Clinical Laboratory Improvement Amendments of 1988; Final Rule.
Fed Register. 1992(Feb 28): [42CFR493.801 (B)(4)]

IX. STAKEHOLDERS

N/A

Policy Title	Laboratory Quality Control Policy	Policy #	LAB1857
Responsible	Laboratory Director	Revised/Reviewed	<u>04/2020</u> <u>10/31/2022</u>

I. PURPOSE

To ensure that quality control processes effectively monitor the accuracy and precision of patient results.

II. POLICY

The following procedures will be in effect in order to insure quality lab results.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. It is the policy of WCH Clinical Laboratory that:

1. Each department will establish and maintain quality control logs appropriate to clinical discipline. During orientation and following departmental changes, staff will be in-serviced in departmental QC guidelines, logs and documentation of corrective action.
2. Quality control material will be run and recorded by staff assigned to each department according to the schedule established by the Section Head. Corrective action will be recorded as necessary. Examples of corrective action are:
 - a. Re-run controls
 - b. Re-calibrate analyte
 - c. Replace reagents
 - d. Perform preventative maintenance.
 - e. If all of above fails, send stat specimens to reference lab.

Quality control material run by non-licensed personnel will require approval and sign-off by licensed staff. Licensed staff will determine, with the Medical Director's assistance, the clinical significance of out-of-control events. Some errors may require repetition of previous testing or delay of test results while system errors are identified and corrected.
3. For quantitative test results, a minimum of two levels of controls are required to be run every 24 hours.
4. For qualitative test results that have internal QC build in, QC will be run every 30 days and per manufacture's requirement.
5. For tests approved with Individualized QC Plan (IQCP under Clinical laboratory Improvement Amendments, CLIA 42CFR493, 1250), please refer to IQCP Policy LAB0002.
6. The QC is run after calibration, change of reagent, or major maintenance on instruments.
7. Due to the complexity and the type of QC that is run by Microbiology please refer to department's policies and procedures.

Policy Title	Laboratory Quality Control Policy	Policy #	LAB1857
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8. At the beginning of each workday, the first CLS scheduled in each department will review the previous day's QC and document any errors or omissions. Any errors/changes to previous day's QC should be made by the CLS who ran the QC material, unless the Section Head requires that the correction be made on an immediate basis.
9. Cumulative QC logs are reviewed by each Section Head on a monthly basis. Technical errors will be brought to the CLS's attention by the Section Head.
10. The Laboratory Director or designee will review action items identified by the Section Head and will complete the Laboratory Quality Control Review (LQCR) form (see attached).
11. The Medical Director will review LQCR forms on a quarterly basis and offer suggestions and provide oversight of cumulative quality control.

B. Evaluation of Control Results:

1- Two Levels of Control

Rule	Violation
1-2 S	If one point is outside ± 2 standard deviations, this warning rule should trigger careful inspection of the data by the rejection rules listed below. If no other rules are broken, results can be accepted.
1-3 S	This rule applies when a control result falls outside of the 3s limit, either above or below the mean. The run should be rejected. Usually, this indicates that a random error has occurred.
2-2 S	This rule applies when two consecutive results exceed the +2 or the -2 standard deviation limit. The controls could be normal or abnormal (across runs), or one of each (within a run and both outside the same 2SD). A violation of this rule usually indicates a systematic error. The run is rejected.
R-4 S	This rule applies when the difference between the highest and lowest result of a run exceeds 4 standard deviations. This rule detects random errors and applies within one control level (i.e., day 3 the control result falls above +2 SD and day 4 the control result falls below -2 SD) or across two control levels within one run such (i.e., day 6 the high control is above +2 SD and the normal control is below -2 SD). The run is rejected.
4-1 S	This rule applies when four consecutive control samples all exceed the +1 or the -1 limit. The controls could be normal, abnormal, or a combination of the two. This rule detects systematic errors. The run is rejected.
8x	This rule applies when 8 consecutive controls fall on the same side of the mean, either above or below. The rule could also apply if 4 consecutive controls fall on the same side of the mean with both controls. This rule detects a systematic error. The run is rejected.

Policy Title	Laboratory Quality Control Policy	Policy #	LAB1857
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1- Three Levels of Control

Rule	Violation
1-3 S	This rule applies when a control result falls outside of the 3s limit, either above or below the mean. The run should be rejected. Usually, this indicates that a random error has occurred.
R-4 S	This applies if any 2 of the 3 controls within a run exceed 4 SD (One control is $>+2$ SD and another control within the same run is >-2 SD). Random Error
2 of 3 2-2S	2 of the last 3 values across runs are outside the same 2 SD or within a run, 2 of 3 values are outside the same 2 SD. Systematic Error

C. Quality Control Decision Criteria and Corrective Action:

- 1- Use the Westgard rules to determine acceptance or rejection of QC results.
- 2- Acceptance Criteria (In Control):
 - f. Use the R 1-2 S rule as a warning rule.
 - g. The CLS checks for violations of R 4-1 S and R8x.
 - h. If there are none, accept the run and report patient data.
- 3- Rejection Criteria (Out of Control):
 - a. Treat a violation of R 1-2 S rule as "Warning" and inspect the control data with other control whenever a run is violated, do not report patient results without investigation and documentation.
 - b. Not the following Consideration:
 - Check that the proper reagent was used.
 - Check if reagent prepared correctly and when placed in service.
 - Check control material for deterioration or contamination.
 - Check recent activities that might have caused a shift (room or refrigerator temperature, old reagent used, diluents used to make up control, voltage fluctuations, etc.)
 - Check standards and standard curve for deterioration.
 - Review individual procedures and manufacture's package inserts
 - Consult with section head or call Technical Support
- 4- Step by step procedure to make QC decisions:
 - a. Analyze the two or three control materials.
 - b. Test control results with the R 1-2S rule.
 - 1) Accept the run if both controls are within ± 2 SD of their mean.
 - 2) If one or more control results exceeds the ± 2 SD limits, do not report the patient's results. Inspect the control data further, using the additional control rules.
 - c. Accept the run when none of the rules indicates a lack of statistical control.
- 5- If the run is rejected:
 - 1) Hold the patient results until the out of control situation is resolved.
 - 2) Resolve and document out of control situations.
 - 3) Reanalyze patient samples in the rejection run:
 - a) Rerun 5 random patient sample since last successful QC run to determine if all patient samples during QC out period need to be rerun.

Policy Title	Laboratory Quality Control Policy	Policy #	LAB1857
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- b) Use the attached "Data Comparison" form to determine whether the difference between the original and duplicate results is considered to be clinically significant or not. If it is determined that all re-run results show no statistical or clinical difference, no need to repeat more patients. If there is any concern, run 5 additional patients. If 90% or greater show no clinical or statistical difference report results. Consult with the section head if there are any doubts in retesting the volatile analytes such as alcohol, ammonia and etc.

- 6- All out of control and corrective action must be documented in the "Remedial Action Log" to be reviewed by the CLS and the Chemistry Section Head.

V. Attachment:
Three

VI. REFERENCES

Westgard JO, Barry PL. Improving Quality Control by use of Multirule Control Procedures. Chapter 4 in Cost-Effective Quality Control: Managing the quality and productivity of analytical processes. AACC Press, Washington, DC, 1986, pp.92-117.

https://www.labce.com/spg113780_westgard_multi_rule_approach.aspx

https://www.labce.com/spg574557_westgard_multi_rule_approach_continued.aspx

VII. STAKEHOLDERS
N/A



CLINICAL LABORATORY QUALITY CONTROL REVIEW FORM

Month:

Section (circle): Transfusion Services

Microbiology

Reviewed by:

1. Issues identified:

2. Were patient results released prior to resolution of QC problem? If so, indicate clinical significance, if any, or justification for release (indicate date and analyte):

3. Resolution of issues



CLINICAL LABORATORY QUALITY CONTROL REVIEW FORM

Month:

Section (circle): Hematology

Chemistry

Urinalysis

Reviewed by:

1. Shifts or trends noted and resolutions (indicate date and analyte).
2. Were patient results released prior to resolution of QC problem? If so, indicate clinical significance, if any, or justification for release (indicate date and analyte):
3. Non-compliance with Quality Control Policy and resolution:

DATA COMPARISON

DATE:

TEST:

INSTRUMENT:

PATIENT	A 1st Value	B 2nd Value	C Ave of A+B	D A-B	E 2X sq rt of C	F Is E>=D?	G Clinically the same?
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Run 5 patients. If the answer to F and G is yes for all 5 pairs of results then they show no clinical or statistical difference, patient results are acceptable to report. If there is any concern run 5 more patients. If 90% or greater show no clinical or statistical difference report results. Consult with supervisor if there are any doubts.

Policy Title	Diseases Reportable	Policy #	LAB1861
Responsible	Laboratory Director	Revised/Reviewed	<u>10/18/2022</u> 11/2 020

I. PURPOSE

To assure prompt initiation of medical treatment and reduce potential spread of infection.

II. POLICY

All positive reports (both inpatient and outpatient) which qualify as a reportable disease under State of California, Department of Health Services regulations will be reported by laboratory staff.

III. DEFINITIONS

N/A

IV. PROCEDURE

Within one (1) working day from the time the infection is identified, laboratory staff will initiate a Confidential Morbidity Report (CMR) on all infections indicated below that are either isolated by or reported through this clinical laboratory. The report must include:

- a. Name
- b. Gender
- c. Age or Date of Birth of the patient
- d. Name
- e. Address
- f. Telephone number of the physician/healthcare provider or other authorized person who submitted the specimen
- g. Date the specimen was obtained
- h. Reportable disease or condition (see Reportable Communicable Diseases list attached).

For reports initiated by the Microbiology or Chemistry Departments, the CMR will be completed by either a CLS or a technician working under the technologist's direction.

For reports initiated by the Serology or Hematology Departments, the CMR will be completed by a CLS.

For reports initiated by the Specimen processing Department, the CMR will be completed by a technician and initialed by a CLS.

For reports on inpatients and Emergency Department patients, the CMR will be faxed to the Santa Cruz County Health Dept and a copy placed in the Infection Control Practitioner's box in the Blood Bank Department. A copy will also be retained in the Specimen Processing Dept of the lab. The Infection Control Practitioner will review the CMR and add additional pertinent information before mailing the CMR. Any communication between the physician and the laboratory must be noted and initialed on the CMR.

Policy Title	Diseases Reportable	Policy #	LAB1861
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For reports on outpatients, the CMR will be completed and mailed or faxed by laboratory staff.

Mailing address: Santa Cruz County Health Department
Communicable Disease Unit
1080 Emeline St.
Santa Cruz, CA. 95060
(831) 454-5049

Many infectious disease isolates are considered panic values by this laboratory. Panic values on inpatients or Emergency Department patients must be called per standard laboratory policy; in addition, panic values for infectious diseases or conditions must be called to the Infectious Disease Practitioner (ext. 1255). CLS's are urged to rely on their professional experience and education in determining which other diseases and conditions warrant direct communication with the physician or other health care provider.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Lab Technician/Phlebotomist Performance Standards	Policy #	LAB1866
Responsible	Laboratory Director	Revised/Reviewed	01/2021 <u>12/15/2022</u>

I. PURPOSE

To obtain patient blood specimens in a timely and efficient manner and to provide high-quality patient care by improving test turn around time. To improve the effectiveness of the Clinical Laboratory Scientists by the timely delivery and processing of laboratory specimens.

II. POLICY

A. First Morning Inpatient Draws.

1. The Night phlebotomist will sort and prepare labels for the AM phlebotomists. Each phlebotomist will be given approximately the same workload based on the draw time standard. This should normally be between 12-17 patients. Difficult draws as well as covid draws should be distributed equitably.
2. The Night phlebotomist will also identify line draws by 0300 by calling the floors, take the tubes to the RNs, and return the sort slips. The Night phlebotomist will assist with morning draws beginning at 0400 by taking 14 to 17 draws. The Night phlebotomist will complete their draws by 0600, pick up the AM phlebotomist(s) samples for delivery to the lab, and receive the samples in the LIS by 0630.
3. The scheduled 4 AM phlebotomist will arrive to work on time and be on the floor no later than 4:10 am.
4. The second scheduled AM phlebotomist will go to CCU, pick up any line draws and draw any non-line draw patients. These samples must be returned to the lab and either received or dropped off. The second scheduled AM phlebotomist will then proceed to the floor as needed and cover on patient draws when 4AM is on break.
5. All phlebotomists will bring their completed draws down no later than 06:40 am or call for a pick up if the workload is heavier than usual.
6. Ideally, all morning draws must in the processing area by 7:00 am.

B. Neonatal Testing:

1. ICN patients will be drawn with morning rounds

C. Outpatients:

The outpatient door opens 0630 AM-1700 AM Monday through Friday.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Blood Drawing Standard:

- 1- Refer to LAB1851 policy
- 2- The following blood drawing standards are in effect:

Inpatients:

First Morning Draws. Each phlebotomist should have between 10 and 15 patients to draw. It

Policy Title	Lab Technician/Phlebotomist Performance Standards	Policy #	LAB1866
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is expected they will draw an average of 10 patients/hour. The morning phlebotomists are expected to have/send their specimens in the lab by 06:40 am.

- An average patient should take no more than 6 to 10 minutes to draw.
- Infants should take no more than 15 minutes to obtain a capillary specimen.
- Neonatal Screening draws should take an average of 12 minutes per specimen.

Outpatients:

The average drawing time for outpatients should be 6 to 10 minutes after the orders are entered in LIS. Infants should take an average of no more than 12-15 minutes after the orders are entered in LIS.

B. Receiving Specimens: In all cases the drawing phlebotomist will receive their specimens upon entering the lab and distribute specimens to the appropriate sections. Exceptions are in effect if there is a specimen processor who is available to assist with receiving samples, while the lab technician is required to respond to an Emergency code or a STAT draw. The draw times will be entered into the computer when receiving specimens.

C. Response times:

1- Refer to LAB1852 Policy

2- If timed draws are drawn after the requested time, check with nursing or appropriate CLS Section Head or Charge CLS. Critical time draws will be drawn on the hour requested (i.e., Therapeutic drug levels).

D. Failure to meet Standard

Isolated incidents. Written documentation is required stating the reasons the phlebotomist was unable to meet the standard.

Patterns of incidents. Anyone showing a pattern of below standard practice will be met and interviewed by the Laboratory Director or Assistant Director.

Consistent below standard performance will result in counseling and/or disciplinary action.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Reference Laboratory Approval	Policy #	LAB1909
Responsible	Laboratory Director	Revised/Reviewed	<u>10/2022</u> 11/2020

I. PURPOSE

To use approved and accredited reference laboratories.

II. POLICY

Accredited Reference Laboratories must be approved.

III. DEFINITIONS

N/A

IV. PROCEDURE

- A. Reference Laboratories that are chosen for service for WCH laboratory must be approved by the Medical Director and the Medical Staff.
- B. Reference Laboratories will be chosen based on their ability to best meet the needs of the hospital patients and physicians.
- C. All Reference Laboratories must be accredited by CLIA.
- D. Pathology and Cytology is referred to APMG.
- E. For Blood Bank testing that is beyond the scope of WCH laboratory, specimens will be sent to the American Red Cross.
- F. Quest Diagnostics is the primary reference laboratory. Focus and Specialty are secondary reference laboratories.
- G. CHOMP and Dominican are used in STAT and urgent situations when analyzers or reagents are compromised.
- H. WCH lab will obtain the following documents from all reference labs used:
 - CLIA certificate
 - California licensure
- I. Medical Executive Committee approval for currently utilized reference labs is filed in Lab Admin.

I. REFERENCES

N/A

II. STAKEHOLDERS

N/A

Policy Title	Reference Laboratory Testing	Policy #	LAB1910
Responsible	Laboratory Director	Revised/Reviewed	<u>10/31/2022</u> 11/2/20

I. PURPOSE

To establish guidelines for billing clinical laboratory tests referred to other laboratories in accordance with CMS guidelines.

II. POLICY

1. Reference Labs are used for testing beyond the scope of WCH lab for emergency testing when analyzer or reagents fail, and for reference testing for analytes without proficiency materials.
2. Clinical laboratory tests referred to another lab for testing will be billed according to the criteria described in this procedure.
3. WCH may not charge any payer more than the charge billed to the laboratory by the performing laboratory.
4. When a specimen is obtained from an inpatient or outpatient of the WCH and is referred to another laboratory for testing, WCH must bill Medicare for laboratory services.
5. Date of Service - Per Medicare guidelines, the lab date of service (DOS) is generally the date the specimen was collected, however, there are exceptions to this rule. Refer to the Laboratory Compliance Plan for complete guidance.
6. WCH Laboratory must identify the reference laboratory(s) that is utilized for each test.
7. WCH must obtain and/or verify that documented CLIA (Clinical Laboratory Improvement Act) and/or CAP (College of American Pathologists), TJC (The Joint Commission), COLA (Commission On Laboratory Accreditation) certificate information is available for each testing specialty used by each reference laboratory identified in previous step.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Any test that cannot be performed at WCH laboratory must be sent to a reference laboratory.
 - a. Reference laboratories currently approved for use by WCH Lab include:
 - i. Quest Diagnostics (primary reference lab)
 - ii. Community Hospital of the Monterey Peninsula (CHOMP) Lab
 - iii. Dominican Hospital Lab
 - iv. APMG
 - v. Stanford Health Services
 - b. Additional reference laboratories will be considered on a case-by-case basis and must be approved by the Lab Director.
 - c. Use of additional reference labs may be required for any of the following:
 - i. Specialized esoteric testing
 - ii. Physician request

Policy Title	Reference Laboratory Testing	Policy #	LAB1910
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- d. Submission of specimens to reference laboratories must follow reference laboratory specific test requirements and guidelines. These requirements must be followed precisely to avoid test-not-performed (TNP) issues.
 - e. In the event of instrument or reagent failure, STAT and urgent tests should be sent to CHOMP or Dominican Hospital.
 - i. Dominican is primary. CHOMP is secondary
 - ii. Only STAT and urgent tests should be sent. All others can be batched or saved, depending on length of instrument or reagent downtime. CLS is to make determination with secondary approval of the Laboratory Director or Medical Director.
 - iii. STAT reports from CHOMP or Dominican are to be communicated to the nurse or physician immediately.
- 2. Reference laboratory reporting varies based on the laboratory:
 - a. Quest will report tests through the Quest computer system which is installed in Specimen Processing. Reports are printed in the morning and distributed as appropriate.
 - b. STAT tests from CHOMP and Dominican will be received via fax. Results must be distributed immediately.
 - c. All other reference lab results will be received via mail and distributed as appropriate.

V. REFERENCES

1. OIG Model Compliance Plan for Clinical Labs (March, 1997)
2. Medicare Benefit Policy Manual (CMS Pub. 100-2), Chapter 6
3. Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 16, Section 40.

VI. STAKEHOLDERS

N/A

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
Responsible	Laboratory Director	Revised/Reviewed	12/2020 12/15/2022

I. PURPOSE

This document establishes criteria for correct collection of blood specimen by venipuncture for the collection and handling of blood specimens in both outpatient and inpatient settings.

II. POLICY

1. Proper specimen collection and handling are of the utmost importance because significant errors occur in the pre-analytical phase of laboratory testing (i.e. incorrect patient identification, incorrect order of draw. Standard procedures and protocols shall always be followed to prevent errors and to maintain the integrity of the specimens.
2. All patients and laboratory specimens are treated as infectious and handled according to The Watsonville Community Hospital "Standard Precaution Policy".
3. Use AIDET with every patient every time. Use AIDET consistently for organizing patient communication and providing patient with the information and caring relationship that they want and need. The keys to effective patient and customer communication include:

A	ACKNOWLEDGE:	Greet the patient by name. Make eye contact, smile, and acknowledge family or friends in the room.
I	INTRODUCE:	Introduce yourself with your name, skill set, professional certification, and experience.
D	DURATION:	Give an accurate time expectation for tests, and identify next steps. When this is not possible, give a time in which you will update the patient on progress.
E	EXPLANATION	Explain step-by-step what to expect next, answer questions, and let the patient know how to contact you or your manager.
T	THANK YOU:	Thank the patient and/or family. You might express gratitude to them for choosing your hospital or for their communication and cooperation. Thank family members for being there to support the patient.

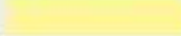
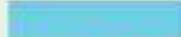











4. Blood Collecting Trays- External area of the phlebotomy tray if not using cart must be cleaned with disinfectant after each patient, before leaving the room. Internal parts of the phlebotomy tray, with normal use, should be cleaned and disinfected on a regular basis. These trays should be spot-cleaned as needed and supplies be refilled at the end of the shift, therefore ready for use by the next shift. If a spill of blood or other types of specimen occurs, STOP right away and disinfect the affected area of the phlebotomy tray.
5. Tourniquets-Use only "single-use" disposable tourniquets, preferably latex-free.

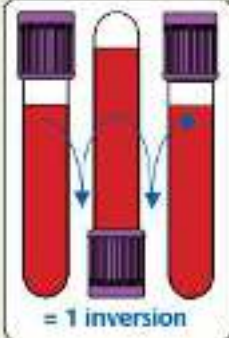
Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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Tourniquets must be discarded immediately when contamination with blood or body fluids is obvious or suspected. Do not leave tourniquets in rooms of psychiatric patients.

6. Ice-Ice or refrigerant should be available for specimens that require immediate chilling.
7. Warming Devices-Warming devices may be used to dilate blood vessels and increase flow. When using commercial warmers, follow manufacturers' recommendations. Warming techniques and devices should not exceed 42 °C.
8. Identify Patient: Identification of the patient is crucial. The phlebotomist must ensure that the blood specimen is drawn from the individual designated on the request form. The phlebotomist must not rely on a bed tag, or on charts or records placed on the bed, nearby tables, or equipment. Check for at least two patient identifiers: full name, date of birth and medical record number as an extra identifier.
9. Arterial punctures should not be considered as an alternative to venipuncture for difficult draws. If this is the only alternative, consult with the patient's physician.
10. Mastectomy: A physician must be consulted before drawing blood from the side on which a mastectomy was performed because of the potential for complications due to lymphostasis.
11. Specimens collected through a hematoma area may cause erroneous test results. Phlebotomy must not be performed on any size hematoma. If another vein site is not available, the specimen is collected distal to the hematoma.
12. To avoid cross-contamination of additives between tubes, blood must be drawn in a specific order. The procedure is the same for all types of tubes or instruments used. It is vital that the order of draw is followed not only to avoid contamination, but also to ensure accuracy of test results. The smallest error could mean that the patient might not receive the most appropriate care and treatment for his specific case. Follow the order of draw for WCH and standardize specimen mixing by following the frequency of inverting the tube.
13. Reconfirm the patient identifiers and demographics when putting any label on the tube. Put your initials, date and time of draw.

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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Closure Color	Collection Tube	Mix by Inverting
BD Vacutainer® Blood Collection Tubes (glass or plastic)		
	* Blood Cultures - SPS	8 to 10 times
	* Citrate Tube*	3 to 4 times
 or 	* BD Vacutainer® SST™ Gel Separator Tube	5 times
	* Serum Tube (glass or plastic)	5 times (plastic) none (glass)
	* BD Vacutainer® Rapid Serum Tube (RST)	5 to 6 times
 or 	* BD Vacutainer® PST™ Gel Separator Tube With Heparin	8 to 10 times
	* Heparin Tube	8 to 10 times
 or 	* EDTA Tube	8 to 10 times
	* BD Vacutainer® PPT™ Separator Tube K ₂ EDTA with Gel	8 to 10 times
	* Fluoride (glucose) Tube	8 to 10 times



III. DEFINITIONS

N/A

IV. PROCEDURE

Step 1: Prepare Accession Order

Each request for a blood specimen must be accessioned to identify all paperwork and supplies associated with each patient. Develop your own system to avoid mislabeling.

- Patient's full name and date of birth.
- Identification numbers: Medical record and account number.
- Date and time the specimen is obtained
- Accessioning number
- Authorized health care professional's full name done
- Other information as needed (e.g., special comments: intravenous (IV) site, sampling site if other than arm).

Step 2: Approach and Identify the Patient; Sanitize Hands

The phlebotomist should identify himself or herself, establish a rapport, and gain the patient's confidence. Collectors should disinfect hands between patients in accordance with the Centers for Disease Control (CDC) Hand Hygiene Guideline. The phlebotomist must NOT perform blood collection against the patient or guardian's consent. Instead, report the patient's objections to the physician or nursing station

Inpatient setting:

Greet the patient in a friendly manner. Use AIDET to communicate. Assess any special education issues or age-related care issues the patient may have. Different language and approach will be required for pediatric, geriatric, or developmentally disabled adults.

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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- Compare the patient demographic information on the order/label with information on the patient's wristband.
- Use two (2) patient identifiers, preferably patient name, and medical record.
- Do not proceed with the draw if name on the armband does not match the name on the label. Instead, inform the nursing staff of the discrepancy and wait for the issue to be resolved.

Outpatient setting:

As appropriate, call the patient into the drawing room using the patient's full name. Assess any special educational issues or age related care issues the patient may have, and introduce yourself and using language appropriate to your assessment

- Ask the patient to sit in a phlebotomy chair.
- Ask the patient to repeat their full name and confirm that it matches the name on the order/labels.
- Confirm the patient's identity with a second identifier, such as the patient's date of birth, compare also to patient's armband & requisition.
- Use AIDET when communicating with the patient.
- Give the patient your full attention.

The following steps are suggested sequence for ensuring patient identification, regardless of the clinical setting:

Patient Who Is Conscious

- 1) Ask the outpatient to give full name, address, identification number, and/or birth date.
- 2) Compare this information with the information on the request form.
- 3) Ask the inpatient for the same information and compare this with the information on the request form and the patient's identification bracelet, which must be attached to the patient.
- 4) Report any discrepancy, however minor, to the responsible person in the area and have the patient identified by name and identification number before drawing any specimen. Any discrepancies must be resolved before specimen collection. When drawing from cognitively impaired patients in these environments, ask a caregiver or family member to identify the patient by name, address, identification number, and/or birth date. Compare these data with the information on the request form.

Patient Who Is Unconscious, Too Young, Cognitively Impaired, or Does Not Speak the Language of the Phlebotomist

- 1) Ask the nurse, a relative, or a friend to identify the patient by name, address, identification number, and/or birth date.
- 2) Document the name of the verifier.
- 3) Compare these data with the information on the request form. For inpatients, compare these data with those on the patient's identification bracelet, which must be attached to the patient.
- 4) Report any discrepancy, however minor, to the nurse responsible for the patient. Have the patient identified by name and/or identification number before drawing any specimen.

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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Patient Who Is Semiconscious, Comatose, or Sleeping

- 1) Sleeping patients should be awakened before drawing blood.
- 2) The phlebotomist must take special care when drawing blood from semiconscious or comatose patients to anticipate any unexpected movements or jerking, either while introducing the needle or while it is in place in the arm.
- 3) A gauze pad should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidentally goes much deeper into the arm, the phlebotomist must inform the physician or nursing station.
- 4) If unable to identify the patient, then contact the nurse or physician. Document the name of the verifier.

Step 3: Apply Tourniquet and Select Vein

- 1) Place a tourniquet on the patient's arm. Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.
- 2) Choose the vein that feels the fullest.
- 3) Ask the patient to make a fist that makes the vein more prominent and easier to enter.
- 4) Avoid vigorous hand "pumping". It can cause changes in the concentration of certain analytes in the blood.
- 5) Feel firmly and always feel for the median antecubital vein first; it is usually bigger and anchored better, and it bruises less. The cephalic vein (depending on size) is the second choice over the basilic vein because it does not roll or bruise easily. The bend of the elbow (antecubital fossa) or slightly below, is the best place to make a puncture.
- 6) When antecubital veins are not acceptable or unavailable, veins on the back of the hand are also acceptable for venipuncture. Veins on the underside of the wrist must not be used, as nerves and tendons are close to the surface of the skin in this area.
- 7) Alternative sites, such as ankles or lower extremities, must not be used without the permission of the physician because of the potential for significant medical complications (e.g., phlebitis, thrombosis, tissue necrosis).

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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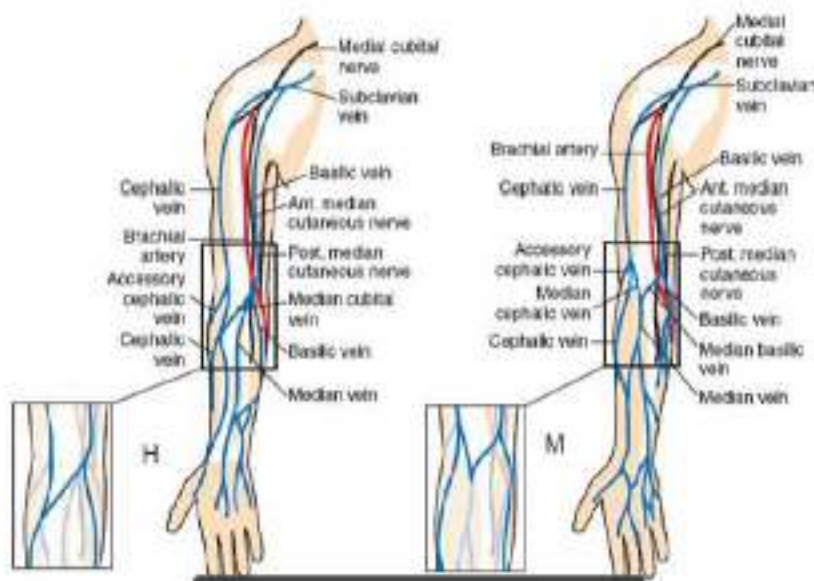


Figure 1. Superficial Veins of the Anterior Surface of the Right Upper Extremity.

(From: McCall RE, Tankersley CM. *Phlebotomy Essentials*. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008. Adapted with permission from Lippincott Williams & Wilkins. <http://lww.com>.)

Precautions

When Using a Tourniquet

Tourniquet application should not exceed one minute as localized stasis with hemoconcentration and infiltration of blood into tissue can occur. This may result in erroneously high values for all protein-based analytes, packed cell volume, and other cellular elements.

If a tourniquet has been in place for longer than one minute, it should be released and reapplied after two minutes. If the patient has a skin lesion at the intended tourniquet location, consider an alternate draw site, or apply the tourniquet over the patient's gown; alternatively, a piece of gauze pad or paper tissue should be used so the skin is not pinched.

When Selecting Vein

Select the vein carefully. The brachial artery and several major nerves pass through the antecubital area. Accidental arterial puncture and nerve injury are risks of venipuncture. Prioritizing veins can minimize the potential for accidental arterial puncture and for nerve involvement. In addition, avoid veins that are in close proximity to an artery, as indicated by the presence of a pulse.

Accidental Arterial Puncture

If during the procedure, accidental arterial puncture is suspected (eg, rapidly forming hematoma, rapid filling of tube), discontinue the venipuncture immediately. Remove the needle, and apply direct forceful pressure to the puncture site for a minimum of five minutes until active bleeding has ceased. The nursing staff and physician must be notified and the incident documented according to institutional policy.

NOTE: Consult with supervisory personnel to determine the suitability of the suspected arterial specimen for testing.

Nerve Injury

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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If the patient feels a shooting, electric-like pain, or tingling or numbness proximal or distal to the puncture site, terminate the venipuncture and remove the needle immediately. Repeat the venipuncture in another site if needed. Document the incident and direct the patient to medical evaluation if indicated.

Procedure for Locating Veins

- Typically, a tourniquet is used to aid in the selection of a vein site unless specific tests require tourniquets not be used (e.g., lactate).
- A tourniquet is not necessary if veins are large and easily palpated. However, if only the basilic vein is visible without a tourniquet, one must be applied so the availability of safer veins (e.g., median and/or cephalic) can be assessed.
- Palpation is usually performed using the index finger. The collector's thumb should not be used to palpate because it has a pulse beat. In addition to locating veins, the palpation pressure helps to differentiate veins from arteries, which pulsate, are more elastic, and have a thick wall. When vein selection, cleansing, and access take longer than one minute, the tourniquet must be released and reapplied after two minutes to minimize the effect of hemoconcentration.

Step 4: Put On Gloves

The phlebotomist must put new gloves on before the venipuncture is performed with consideration for latex sensitivity.

Step 5: Cleanse Venipuncture Site

- Using an alcohol pad or cotton ball saturated with alcohol, cleanse the area by moving the pad in a circular motion from the center of the vein site outward. The area must be allowed to dry. Do not touch the skin after the site has been cleansed unless you have similarly prepared your gloved finger. (Use a chloraprep wipe when drawing blood cultures).
- Inspect the needle, syringe or evacuated tube before performing the venipuncture:
 - The appropriate needle is attached to the syringe or the evacuated tube holder and threaded into the holder until it is secure; the needle sheath will lock into the holder. If the needle touches anything but the sterile, cleansed site, it should be changed.

Cleaning Venipuncture sites For Blood Culture Collection

In order to minimize the risk of contamination with skin flora, venipuncture sites for blood culture require a 30- to 60-second friction scrub and disinfection with an appropriate disinfectant. Tincture of iodine, multiple isopropyl alcohol preps, chlorhexidine gluconate, and povidone 70 % ethyl alcohol-combination are equivalent. Iodine and chlorhexidine preparations require at least 30 seconds of skin contact to disinfect the site. Because of iodine's effect on the thyroid and liver and the potential for allergic reactions, iodine should be removed from the skin once the procedure is complete.

Manufacturers do not recommend using chlorhexidine gluconate on infants less than two months of age. When using commercially packaged prep kits, follow the manufacturer's instructions for use. Preparing the site typically includes an initial cleansing with 70% isopropyl alcohol, allowing it to air dry, followed by a friction scrub and application of an iodine or chlorhexidine compound. The antiseptic should remain in contact with the skin for at least 30 seconds. Strict aseptic technique should be used throughout the procedure. Blood culture bottles can be filled by drawing blood into a sterile syringe and then transferred with a safety transfer device. Bottles can also be filled directly through a winged collection set attached to a tube holder.

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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Blood can be drawn directly into collection tubes containing sodium polyanetholsulfonate (SPS), then transferred to blood culture medium, but should never be drawn into tubes containing anticoagulants not designated for blood culture collection. *Unless approved by the manufacturer, filling bottles directly through a needle/tube-holder assembly is not recommended because of the risk of reflux of the broth media back into the vein and the difficulty of assessing the volume of blood drawn.* (See Blood Culture Collection Procedure)

Touching the Site after Cleansing

Clean venipuncture site again if the venipuncture proves difficult and the vein must be touched again.

Step 6: Perform the venipuncture

- 1) Evacuated tube method: Grasp the patient's arm firmly, using your thumb to draw the skin taut. The vein is entered with the bevel of the needle upward. Follow the order of draw. Refer to the order of draw policy. The tube should be filled until the vacuum is exhausted and the blood flow ceases, to ensure a correct ratio of anticoagulant to blood. After each tube is drawn, an additive should be mixed immediately by gently inverting the tube at least 5 times. Never shake a tube after collecting a blood specimen.

Other methods:

A winged infusion set with Luer adapters can be used instead of a syringe and needle for very difficult veins, and is especially helpful when collecting blood from neonates.

If all possibilities have been exhausted, and you have not been successful at obtaining a specimen after two (2) attempts, enlist the aid of a coworker or supervisor. Inform the nurse caring for the patient and complete an Unable to draw slip.



Figure 2. Proper Angle of Insertion. (From McCall RE, Tackesley CM. *Phlebotomy Essentials*. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008. Reprinted with permission from Lippincott Williams & Wilkins. <http://lww.com>.)



Figure 3. Improper Angle of Insertion. (Figure contributed by the Center for Phlebotomy Education, Inc.)

- 2) End the procedure:

As soon as the phlebotomy is completed and before the needle is removed from the patient, gently remove the tourniquet. Holding a piece of gauze over the puncture site, withdraw the needle following the same path of entry. Secure the safety lock on the needle. Apply pressure to the site until bleeding stops. When the active bleeding has stopped, apply adhesive tape and gauze over the site. Use a transfer device if necessary.

Outpatients: Instruct the patient not to carry anything heavy with the arm used for the procedure for about an hour.

- 3) Mix tubes and label at the patient's bedside or at the drawing chair:

Policy Title	Guidelines for Performance of a Venipuncture	Policy #	LAB2363
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- 4) Labels must include the patient's last, then first name, date of birth or medical record number, the date and time of collection and the phlebotomist's PIN code or initials.
- 5) Re-verification process. Reverify labeled tubes against patient's armband for inpatient. If outpatient, let the patient re-state his/her full name and DOB.
- 6) Dispose of contaminated materials and supplies appropriately:
- 7) Use designated biohazard containers and exchange for empty containers when $\frac{3}{4}$ full.
- 8) Leaving the patient:
- 9) Outpatient: Thank the patient for his or her cooperation.

Inpatient: Leave the patient's room in the same condition as when you found it; return tables and light to original positions. Thank the patient for his or her cooperation.

V. REFERENCES

1. CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition. CLSI document H03-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

VI. STAKEHOLDERS

N/A

Policy Title	Approved Sites and Conditions for Phlebotomy	Policy #	LAB2364
Responsible	VP, Ancillary Services	Revised/Reviewed	<u>10/31/2022</u> 11/1/20

I. PURPOSE

To define appropriate collection sites for phlebotomy.

II. POLICY

Due to the potential of contamination with intravenous fluids, and the potential physical risk of phlebotomy at every body site, the following recommendation from the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) will be adopted as policy.

- a) **Fistula:** an arm with a fistula should not be used for blood drawing. Specimen should be drawn from opposite arm. A fistula is an artificial shunt connection done by a surgical procedure to fuse the vein and artery together. It is used for dialysis only. Care must be taken of the fistula, as it is permanent.
- b) **Intravenous Fluids:**
When an intravenous solution is being administered in a patient's arm, blood should not be drawn from that side. It has been shown that blood drawn from above the I.V. site can be diluted/contaminated with the fluid being administered. Test results will be erroneous and thus misleading to the physician or nurse. The phlebotomist should look for an alternative blood-drawing site in the opposite arm. On occasion, intravenous solutions will be running in both arms. In this case, satisfactory specimens can be obtained by doing the following:
 1. Ask the nurse to turn off the I.V. for at least 2 minutes before venipuncture.
 2. Select a venipuncture site at least 3 inches below the I.V. in a vein other than the one with the I.V.
 3. Apply the tourniquet below the I.V.
 4. Perform the venipuncture. Draw and discard 5ml. Of blood before drawing test specimens.
 5. Indicate as a specimen comment that this specimen was obtained from an arm which had an I.V. running.
- c) **Phlebotomy Sites:** Veins of the arm are considered optimal locations from which to obtain specimens. Hands are considered alternate drawing sites. A foot or leg vein should never be used. Should a skilled phlebotomist be unable to obtain a specimen, the patient's nurse or physician should be informed. On occasion, the physician may approve an arterial puncture, performed by a Respiratory Therapist with a phlebotomist assisting, as an acceptable means of obtaining a specimen, or the physician may wish to obtain the specimens themselves.
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- d) **Indwelling Lines, Heparin & Saline Locks:** Blood should not be collected from these lines or locks due to the possibility of contamination. Phlebotomists are not trained to collect blood through these devices.

III. REFERENCES

N/A

IV. STAKEHOLDERS

Policy Title	Approved Sites and Conditions for Phlebotomy	Policy #	LAB2364
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N/A

Policy Title	Newborn Screening	Policy #	LAB2365
Responsible	Laboratory Operations Manager	Revised/Reviewed	01/27/2021 10/31/2022

I. PURPOSE

The intent of this policy is to provide guidelines for filter paper newborn screenings including specimen collection, sample handling and preparation, timing and shipment, and specimen tracking.

II. PRINCIPLE

The timing of specimen collection and the quality of sample submitted for the newborn screening affects the accuracy of the test results. Less-than-optimal specimens may yield unreliable, misleading, or clinically inaccurate results. The potential exists for missed or late diagnosed abnormalities and/or falsely positive results.

III. CLINICAL SIGNIFICANCE

Newborn screening is an essential public health activity focused on testing every newborn for certain endocrine, metabolic, and/or congenital conditions which, without early management, can result in significant morbidity and mortality.

The California Department of Public Health's Newborn Screening Program requires that all babies born in California have the Newborn Screening Test before leaving the hospital. This test screens for specific diseases including Phenylketonuria (PKU), Galactosemia, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCADD), Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Primary Congenital Hypothyroidism, Sickle Cell Anemia, Hemoglobin H Disease, Cystic Fibrosis (CF), and Severe Combined Immunodeficiency (SCID).

IV. PROCEDURE

Newborns whose specimen was collected prior to 12 hours of age must have a second specimen submitted.

If a transfusion is anticipated: Collect the specimen prior to the transfusion of red blood cells, even if the newborn is under 12 hours of age. Infants who are transfused with red blood cells (RBC) must have a specimen collected prior to the transfusion.

For newborns transferred to another facility before six days of age:

- The receiving hospital is to obtain a specimen following above guidelines.
- The hospital of birth must complete and send to the Genetic Disease Branch the form "Hospital Report of Newborn Specimen Not Obtained (NBS-NO)" if the baby is transferred without collecting a specimen.

Order in CPOE/HMS. Physicians should use CPOE to order the Newborn Screen Set for a time after the infant is 12 hours old. Laboratory staff will collect specimens once daily.

Policy Title	Newborn Screening	Policy #	LAB2365
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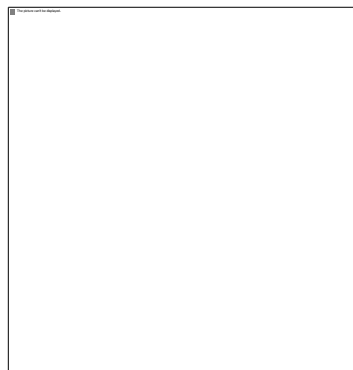
Test Request Form (TRF) must be properly filled out by the nurse attending the newborn. The patient information is used in reporting results to the hospitals and physicians. Information about a specimen, the birth weight, and transfusion status is used in evaluating the test results. The physician's identity is essential to ensure timely tracking of the infant for follow up testing and initiation of therapy for a newborn with one of these congenital conditions. See Attachment A for proper filling out of TRF.

Parent Refusal Parents who refuse to have their newborns tested due to conflicts with parents' beliefs or practices must fill out the "Newborn Screening Test Refusal (NBS-TR)" form from CDPH.

DRIED BLOOD SPOT (DBS) COLLECTION (performed by phlebotomist or ICN nurse)

Instructions for collecting adequate dried blood spots appear on the Test Request Form

1. **CHECK THE EXPIRATION DATE ON THE FORM.** The expiration information is in the lower right-hand corner of the TRF: Example: LOT XXXXXX/XXXXX 2015-02 (the expiration year is 2015, and the expiration month is 02) - do not use as of the **FIRST DAY** of the expiration month. A specimen collected on an expired form will be deemed inadequate and the screen will need to be redone, thus delaying test results.
2. **AVOID TOUCHING THE SPECIMEN COLLECTING AREA** at any time with gloved or ungloved hands. Oil, lotion, or powder from hands or gloves can prevent the blood from spreading evenly and thoroughly. Use unpowdered glove.
3. **BLOOD IS TO BE COLLECTED FROM THE HEEL.** Do NOT collect blood from intravenous/intra-arterial lines, antecubital space or dorsal hand veins unless a heel stick is not possible. Pre-warm the heel for 3 to 5 minutes.
4. **DO NOT USE CAPILLARY TUBES** for collecting the blood to spot on the card. It can damage the filter paper, resulting in an inadequate specimen.
5. **STERILIZE** the skin with alcohol. **WIPE DRY** with a sterile gauze pad.
6. **PUNCTURE** the heel with a disposable lancet deep enough to reach the skin's primary blood supply, yet shallow enough to prevent heel or bone injury.



Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

7. **ALLOW A LARGE DROP OF BLOOD TO ACCUMULATE;** wipe away with a sterile gauze.
8. **ALLOW A SECOND DROP OF BLOOD TO ACCUMULATE, then APPLY THE DROP TO ONE SIDE OF A CIRCLE ON THE NBS COLLECTION CARD.**
9. **ALLOW CIRCLES TO FILL BY NATURAL FLOW** until the circle is completely filled when applying a large accumulated drop of blood to the specimen collection card. Repeat for each circle.

The circles should be filled completely when viewed from both sides. Fill all the circles.

AVOID REPEATED APPLICATIONS of specimen collection card to the heel to fill any one circle.

KEEP AWAY FROM HEAT, LAMPS, DIRECT SUNLIGHT, AND HUMIDITY.

10. AIR-DRY BLOOD SPOTS THOROUGHLY AT ROOM TEMPERATURE (for at least three hours) on a flat surface.
11. Specimens should not be placed in plastic bags or packaging.
12. SEND SPECIMENS TO THE ASSIGNED NAPS LAB WITHIN 24 HOURS OF COLLECTION. Specimens are transported either by a lab courier or by Golden State Overnight (GSO). A transport log, listing the babies whose specimens are in the envelope, must accompany each shipment.

Result Entry

- 1) Laboratory Technician receives the reports mailed from the state. Note: The state also sends a report copy directly to the ordering physician.
- 2) Results are stamped "COMPLETED" in NBS logbook next to the patient name and MRN
- 3) Lab Technician enters canned comment "See Separate Report" in HMS for completion
- 4) Original reports are placed in designated bin for HIM to pick up for record keeping

Pending Result Log

- 1) The pending log for the NBS is reviewed daily by the specimen processor lab technician following Online Specimen Tracking (OST) requirement (17 CCR § 6506). The OST is accessed via the California Department of Health Screening Information System (SIS).

Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

Email Encryption Instructions

IMPORTANT

*** Web email does not work when receiving encrypted messages from CDPH***

1) Step one is receiving the email from support@dhs.ca.gov.
Open this email within 4 days of receipt. Check your spam mail if you did not receive this email.



 support@dhs.ca.gov **Sis Web Admin Utility Notification [secure]**

2) **Double click** on the file located at the subject line. → **message.html**



From: support@dhs.ca.gov
To: Szalay, Malinda (CDPH-PCPH-G201)
Cc:
Subject: Sis Web Admin Utility Notification [secure]
 [message.html](#) (101 KB)

2)

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

Email Encryption Instructions

- 3) **OPEN** the attachment. Some worksites will require you to save the attachment. If this is the case, save the attachment to your desktop and open it from there.



- 4) **Single click** on the **ONE TIME PASSCODE** option located at the bottom of the screen.
- Encrypted message

From
support@dhs.ca.gov

To

To view the message, sign in with a Microsoft account, your work or school account, or use a one-time passcode.

 Sign In



Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

Email Encryption Instructions, cont.

5) **Leave** this Internet browser screen as is and go into your email inbox.

We sent a passcode to melinda.szalay@cdph.ca.gov.

Please check your email, enter the passcode that corresponds with the reference code, and click continue. The passcode will expire in 15 minutes.

Reference code: 0811

Passcode

☐ This is a private computer. Keep me signed in for 12 hours.

6) Wait for the email from Microsoft Office 365. Open the email and copy the passcode.



Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

Email Encryption Instructions

7) Once you have copied the PASSCODE, minimize your email screen, this browser screen should be visible. Paste the PASSCODE into the box, then hit continue.

We sent a passcode to melinda.szalay@cdph.ca.gov.

Please check your email, enter the passcode that corresponds with the reference code, and click continue. The passcode will expire in 15 minutes.

Reference code: 0811



Passcode

☐ This is a private computer. Keep me signed in for 12 hours.



 Continue

Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

User Name and New Temp password info

8) This screen contains your **SIS User Name and temporary password**. The User Name is only your first initial and last name. Copy the Temporary Password and click on the link below.

Sis Web Admin Utility Notification [secure]

Subject: Sis Web Admin Utility Notification [secure]

Here is your User Name and new temporary password for your Sis Extranet Account.

Your User name is: ~~dhsextra~~ kbrusca ← SIS user id is ONLY your first initial and last name. Disregard the dhsextra\

Your New Temporary Password is: 8Ck@g%A26q_ ← Copy the New Temp password

Please click the link below to update your account information and to create your permanent password.
<https://ext2.dhcs.ca.gov/WebPassMgn/default.aspx> ← Click on this link

If the above link is not clickable then copy and paste it into your web browsers address bar.

Note: Please change your password within four (4) days from today's date or your account may become inactive and your password will need to be reset.

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

Required Security screen



DHCS Extranet Password Manager
v1.11.0.0 [Log Off](#)






Entry to Password Manager

WARNING: This is a State of California computer system that is for official use by authorized users and is subject to being monitored and/or restricted at any time. Unauthorized or improper use of this system may result in administrative disciplinary action and/or civil and criminal penalties. By continuing to use this system you indicate your awareness of and consent to these terms and conditions of use.
LOG OFF IMMEDIATELY, if you do not agree to the conditions stated in this warning.

Please answer the Question below
This is called CAPTCHA and it helps us to protect this site. Thank you for your assistance.

What is the sum of three and seven?

Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

SIS Login screen

CA.gov State of California
DHCS Extranet Password Manager
v1.11.0.0 [Log Off](#)

DHCS
Department of Health Care Services

State of California
Seal of the State of California

Save Our Water
Department of Water Resources

Department of Health
Information Systems

DHCS Extranet Login

[Forgot Password](#) [Forgot User Name](#) [Forgot Security Questions](#)

Login To Manage Your Account

User Name ← Enter your SIS User Name

Password ← Paste in the Temporary Password

Email ← Enter your email

← Click

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

SIS Change Password screen



CA.gov State of California

DHCS Extranet Password Manager

v1.1.0.0 [Help PDF](#)






Change Password

Password Policy *(Passwords must meet the following requirements.)*

- Must be between 8 and 30 characters
- Must contain at least:
 - 1 UPPER case letter (A-Z)
 - 1 lower case letter (a-z)
 - 1 digit (0-9)
 - 1 or more of the following \$ # @ + - ! %
- CANNOT contain any SPACES
- CANNOT contain either of these 2 characters < >
- CANNOT IN ANY OF YOUR LAST FIVE (5) Passwords

IT IS REQUIRED TO CHANGE YOUR PASSWORD

New Password

Confirm Password

Follow the password policy above, then click **SUBMIT**.

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

Confirmation that password is changed !



DHCS Extranet Password Manager
v1.11.0.0 [Log Off](#)






Account Management

[Change Password](#)

[Change Security Question/Answer](#)

[Change Email Address](#)

Password Successfully Changed

[Log Off](#) ←

Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

SIS PASSWORD CHANGE SUCCESSFUL

9) Successful completion of your SIS password!

10) Open a **new** Internet Explorer browser session and log into the [SIS](#) Portal page



<https://www.cdph.ca.gov/Programs/CFH/DGDS/Pages/sis.aspx>

Another path to our portal page is to go to Google and search for **SIS CDPH**. The first option is the Screening Information System (SIS) which takes you to our portal page.

11) Save this portal page to your favorites for future access.

Continue



Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

Logging into the SIS Portal Page

- 12) This is the look of the SIS Portal Page. Locate the **Major Links** heading and click on **SIS Online Application**.

California Department of
PublicHealth

I am looking for
▼

I am a
▼

Programs
▼

A-Z Index
▼

Home | Programs | Order for newborn | Genetic Disease Screening | Newborn Information System (SIS)

GENETIC DISEASE SCREENING PROGRAM (GDSP)

Screening Information System (SIS)

Notes: Before you can obtain access to the Screening Information System (SIS) you must read, sign and fax the Oath of Confidentiality or NT Oath of Confidentiality. Contact your program lead to obtain the fax number.

To access the California Codes go to the Official California Legislative Information website.

See the Genetic Disease Screening Program Privacy Policy (PDF).

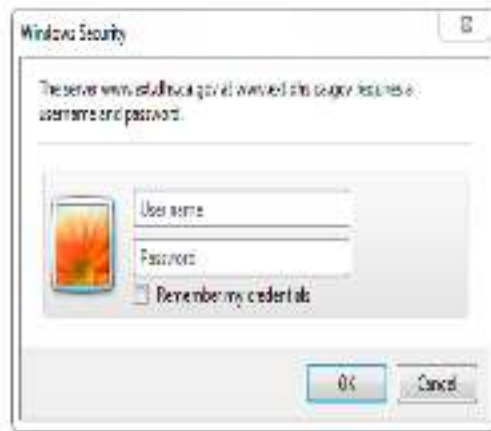
Major Links

- **SIS Online Application**
- Newborn BI Reports
- Update your Personal Information
- Change your Password

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

SIS ACCOUNT LOG IN

- 13) Windows Security box will appear and require the User name. DO NOT type in the dhsextra\ as part of the user name, then enter the new password.



*** Do not check Remember my credentials

****If you enter incorrect credentials, this box will clear itself and allow for another attempt

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

SIS Log in (cont.)

14) A standard Warning message will appear, **click I Agree**.



Policy Title	Newborn Screening	Policy #	LAB2365
---------------------	-------------------	-----------------	---------

SIS compatibility settings; Kaiser users see page 18

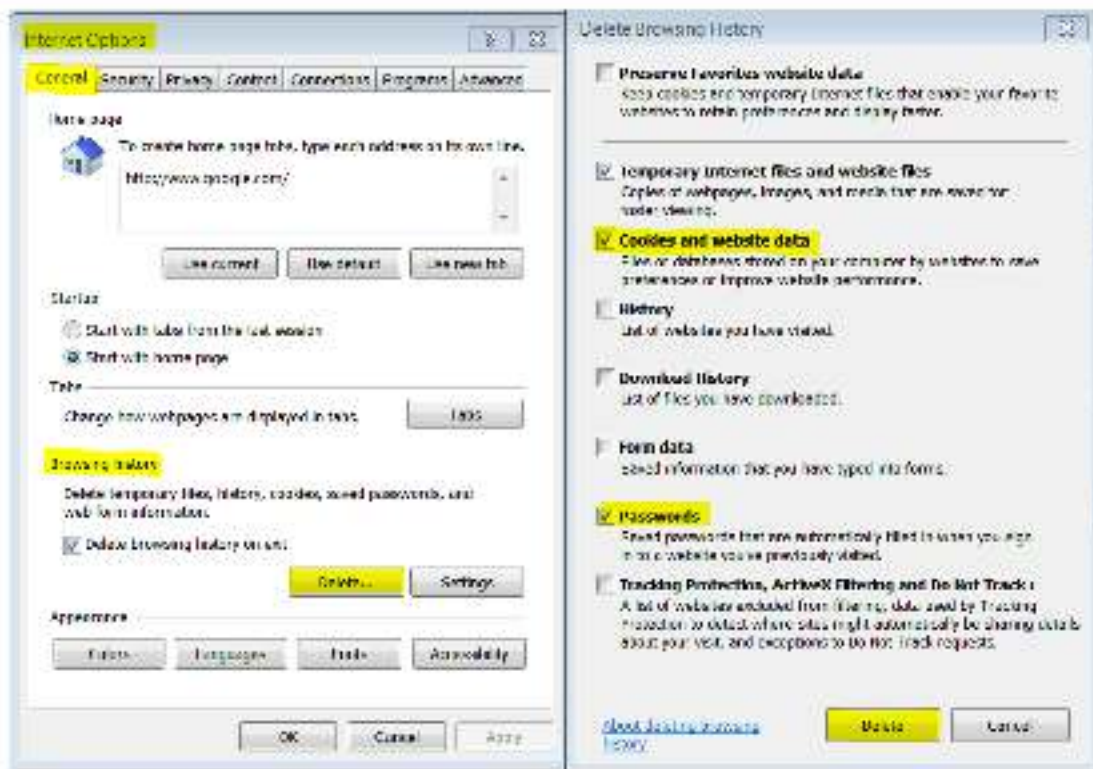
- Operating System = Windows version 7 or higher
- Browser = Internet Explorer versions: 9, 10, and 11 . If your facility does have IE 8 it is possible to force SIS to accept IE8 in the Compatibility View. Open a browser, go into {TOOLS > Compatibility View Settings}. Add ca.gov to accepted websites, then click [Close].



- Turn off pop up blockers {TOOLS > Internet Options > Privacy > turn off pop up blockers}
- Verify the Cookies and Passwords are being deleted in your Browsing History. Open a browser, go into {TOOLS > Internet Options > General tab> Browsing History > Delete}. In the Delete Browsing History ensure Cookies and Passwords have a check in the box next to them, hit Delete. If you have any questions regarding the compatibility settings on your PC please check with your IT department. See screen print on following page.

Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

Deleting Cookies and Passwords

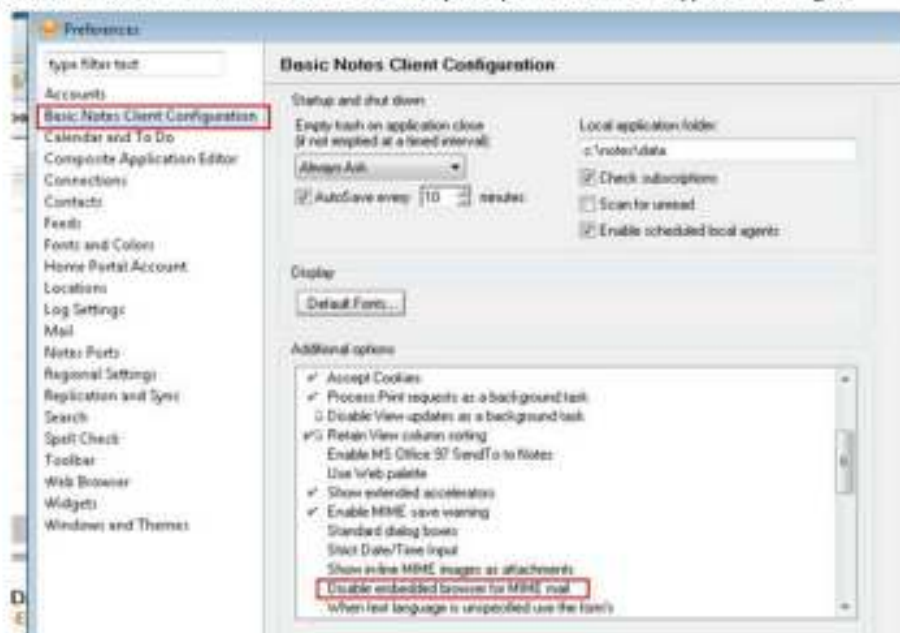


Policy Title	Newborn Screening	Policy #	LAB2365
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Kaiser users special instructions...

Prior to opening any encrypted message from CDPH, it is necessary to modify your Lotus Notes Preferences.

- 1) Select the "File" tab, 2) select "Preferences", look for Basic Notes Client Configuration, 3) Check mark the "Disable embedded browser for MIME mail" (see screen shot below). Close this window.
- 2) Once you log off your current session, this preference change will return to the default settings set by your IT. So you will need to make this modification each time you open a CDPH encrypted message.



Tips

- **Never check the box to Remember your credentials.**



- **It is best to change your own password prior to the 60 day expiration. Go to the SIS portal page and select Change your Password.**



Policy Title	Newborn Screening	Policy #	LAB2365
--------------	-------------------	----------	---------

- 3) New Born Screen (NBS) online Specimen Tracking (OST) quick reference:

NBS Online Specimen Tracking

SCREENING INFORMATION SYSTEM (SIS) FOR GENETIC DISEASE SCREENING PROGRAM

<div style="background-color: #d3d3d3; text-align: center; padding: 2px; margin-bottom: 5px;"> SIS Login and Password </div> <ol style="list-style-type: none"> 1. Open the SIS Portal Page. (http://www.cdph.ca.gov/programs/GDSP/Pages/SIS.aspx) 2. To change the password, click on the Change your password link on the SIS portal and change the password. 3. To reset the password, click on the Forgot your Password? link on the SIS Portal. 4. Enter the information provided initially while setting up the password to obtain a new password. 5. To access the SIS application, click on the SIS Online Application link. 6. If you have questions, contact the SIS Support Desk at: 810-307-0828. <div style="background-color: #d3d3d3; text-align: center; padding: 2px; margin-top: 10px;"> View Specimen Status </div> <ol style="list-style-type: none"> 1. Log into SIS Application. 2. The default landing page is the View Specimen Status screen which displays a list of specimens submitted to GDSP within the last 8 days based on Accession date, specific to the logged on user's hospital. 3. Search to view a specimen by entering a minimum of any two search criteria or entering only the TRFID. <p style="font-size: small;">The system is designed to return a maximum of 100 records. If more than 100 records are found then the system will prompt to provide additional criteria to narrow the search.</p> <ol style="list-style-type: none"> 4. The search results limited to last 180 days are displayed in the Received Specimen List and default sorted by the Specimen Collection Date i.e. newest specimens displayed first. 5. Click any column heading to sort by that column. 	<div style="background-color: #d3d3d3; text-align: center; padding: 2px; margin-bottom: 5px;"> Resend Result Mailer </div> <ol style="list-style-type: none"> 6. Select any specimen by checking the checkbox in the Received Specimen List. 7. Click on the Resend Result Mailer button. 8. The Mailer Creation Date column will show Resend Requested if the request for duplicate result mailer was successful. <i>Note: Mailers are sent out the next business day.</i> 9. For specimens that have Pending or a mailer date less than 14 days from today, the following messages will be displayed: <p style="font-size: small;">If Pending: "The requested mailer has not been generated by SIS. Please wait 14 calendar days after Mailer Creation Date appears before requesting a duplicate mailer."</p> <p style="font-size: small;">If Less than 14 days: "The mailer is requested too soon. Please allow 14 calendar days from the Mailer Creation Date before requesting the mailer again."</p> <div style="background-color: #d3d3d3; text-align: center; padding: 2px; margin-top: 10px;"> Report Specimen Not Collected at Facility </div> <ol style="list-style-type: none"> 10. Select any specimen by checking the checkbox in the Received Specimen List. 11. Click on the Report Specimen Not Collected At Facility button. 12. A confirmation box saying "This will remove the specimen(s) from the list. Click OK to confirm" will be displayed before the user proceeds to confirm the change. The message box will have "OK" and "Cancel" button in order to proceed. 13. The selected specimen will be removed from the Received Specimen List once the user confirms the change.
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1
CDSP Internal Use Only

Policy Title	Newborn Screening	Policy #	LAB2365
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NBS Online Specimen Tracking

SCREENING INFORMATION SYSTEM (SIS) FOR GENETIC DISEASE SCREENING PROGRAM

Report Missing Specimen

1. Log into SIS Application
2. Click **Report Missing Specimen** on the 2nd level menu.
3. Enter the Missing Specimen Details in the Please add newborn details below section.

Please add newborn details below

MR#	<input type="text" value="123456789"/>
MR# last received from the MR#	<input type="text" value="12345"/>
MR# is from Facility	<input type="text" value="123456"/>
Facility Status	<input type="text" value="A"/>
MR#	<input type="text" value="123456789"/>
MR# is day of birth	<input type="text" value="01"/> <input type="text" value="01"/> <input type="text" value="2012"/>
MR# is from Facility	<input type="text" value="123456789"/>
MR# is from Facility	<input type="text" value="123456789"/>
4. Either MR# or NBS Test Request Form (TRF#) is required to input along with other mandatory fields shown with an asterisk.
5. Click **Add to List**.
6. The missing specimen is displayed in the Missing Specimens List grid.

Note: The user can add multiple missing specimens by repeating steps 3 and 5 above.
7. Click on the radio button to update the missing specimen information.
8. Click **Edit**.
9. Update the missing specimen by updating any of the fields displayed in the Please add newborn details below section.
10. Click **Update**.
11. Click **Save** to save all missing specimens reported.

View Missing Specimen Status

12. Click **View Missing Specimen Status** on the 2nd level menu.
13. Default view is a list of all the missing specimens with "Reported" status. The specimens with status other than "Reported" will be shown for 14 calendar days. The view will be specific to the logged on user's hospital.
14. Search for a missing specimen to view its status by entering at least two search criteria or entering only the TRF#.
15. The search results are displayed in the Specimen Reported Missing grid in a two level sort. First level will be on the field Status (Reported status will be shown first) and second level is descending order on the field Date Reported.

Specimen Reported Missing

MR#	<input type="text" value="123456789"/>	TRF#	<input type="text" value="123456789"/>
MR# last received	<input type="text" value="12345"/>	MR# is from Facility	<input type="text" value="123456"/>
MR#	<input type="text" value="123456789"/>	MR# is day of birth	<input type="text" value="01"/> <input type="text" value="01"/> <input type="text" value="2012"/>
MR# is from Facility	<input type="text" value="123456789"/>	MR# is from Facility	<input type="text" value="123456789"/>
16. Click any column heading to sort by that column.
17. SIS will display the status of the missing specimen as one of the following:
 - a) Reported
 - b) Collected at Your Facility
 - c) Collected at Another Facility
 - d) Not Found - Released to the ASD for Follow up

- 4) Hospitals and midwives (facilities) are required to access SIS within 7 days of life to verify that newborn screening specimens are received by a California Newborn Screening Program laboratory. If a specimen has not been received, it is reported as a missing specimen and an investigation is conducted to locate the specimen.

Policy Title	Newborn Screening	Policy #	LAB2365
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V. REFERENCES

- California Department of Public Health, Newborn Screening Program
California State Regulation, 17 CCR 6500
Mosby's Skills, Neonatal Heel Stick
- <https://www.rchsd.org/documents/2017/10/newborn-screening-program-sis-login-instructions-2017-pub.pdf/>
- <https://www.rchsd.org/documents/2019/08/nbs-online-speciman-tracking-quick-reference-guide.pdf/>

VI. STAKEHOLDERS

N/A

Policy Title	Onsite Outpatient Procedure	Policy #	LAB2369
Responsible	Laboratory	Revised/Reviewed	01/2021 12/15/2022

I. PURPOSE

To facilitate onsite outpatient client laboratory work in a confidential, expedient, and orderly manner.

II. POLICY

N/A

III. PERSONNEL

All lab personnel

A. Front Desk Technician

1. Receive outpatient requisition and registration information from patient.
2. Check over paperwork for accuracy, including physician signature, client name, date of birth, address, phone number, test(s) requested, narrative diagnosis or symptom and insurance information.
3. Place patient's name on Outpatient sign in log.
4. Enter all appropriate information from requisition into the HMS laboratory computer. Explain ABN policy and obtain signature if applicable. Print label, place a demographic label on requisition, fold labels and requisition inside out to protect client confidentiality, and place the corresponding number from log on inverted label.
5. Place label and requisition in outpatient sorter in numerical order.
6. Log the phlebotomist initials and time patient called for collection.

IV. DEFINITIONS

N/A

V. PROCEDURE

N/A

VI. REFERENCES

N/A

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
Responsible	Laboratory Director	Revised/Reviewed	<u>12/15/2022</u> 12/2020

I. PURPOSE

To define standards for specimen collection and handling.

II. POLICY

Each test or panel has its specimen requirements listed adjacent to the test. These guidelines are based on professional laboratory standards, and California State licensing requirements. Accurate, valid laboratory test results require that specimens be collected, identified and handled properly. Test results may be delayed, or a specimen may be rejected if it arrived in unsatisfactory condition or is not properly identified.

III. DEFINITIONS

N/A

IV. PROCEDURE

At WCH Laboratory, only blood, urine and throat specimens are collected. All other specimens should be collected at the physician's office. Unless otherwise noted, all specimens should be refrigerated after processing.

LABELING SPECIMENS:

- Tubes of Blood - All tubes of blood must be identified with the patient's name (last, first), date and time drawn, and initials of the phlebotomist.
- Slides - Label the patient's name and date in pencil on the frosted end of the slide. Fix if appropriate. Place in slide container.
- Specimen Containers - (tissue containers, urine containers, culturettes, etc.) Label the container with the patient's name, date and time of collection, and the source of the specimen. When multiple containers are submitted on a patient, each specimen must be individually identified.

TUBE STOPPER COLOR CODING:

Yellow Top (Y)	Gel for serum separation	Invert gently, 4 times. Centrifuge 10 minutes after fully clotted.
Red Top (R)	No anticoagulant	Invert gently, 4 times. Centrifuge 10 minutes after fully clotted.
Blue Top (B)	Sodium Citrate	Invert gently, 8 times.
Lavender Top (L)	EDTA	Invert gently, 8 times.
Green Top (G)	Li Heparin/Na Heparin	Invert gently, 8 times.

BLOOD SPECIMEN COLLECTION:

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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To ensure the integrity of the sample, blood specimens must be collected in the following order, determined by the drawing apparatus.

Order of Draw:

Vacutainer/Winged Transfusion Multidraw Adaptor	Syringe/Winged transfusion Syringe Adaptor
Sterile Red/SST Blue Green Lavender Gray	Sterile Blue Lavender Green Gray Red/SST

WHOLE BLOOD:

When whole blood is requested, select the tube specified and draw the FULL amount indicated. The appropriate color stopper is listed as a specimen requirement beside each test name or profile. Mix the tube well to avoid clot formation which will render erroneous results.

SERUM:

A serum separator tube, yellow top (Y), should be used to obtain serum samples, unless the testing specifies a red top tube (R). The blood should clot for a minimum of 15 minutes, and be centrifuged within an hour. Serum samples collected in a red top tube (R) will require manual separation. After the serum has been processed, the serum should be refrigerated, unless a different temperature is noted. Prior to collection, check whether the patient should be fasting.

Sufficient blood must be drawn to give the volume of serum indicated. Generally, the following amount of serum can be obtained from a yellow (Y) or red top tube (R).

TUBE SIZE	APPROXIMATE AMOUNT OF SERUM OBTAINED
4 ml	1.5 ml
7 ml	3 ml
10 ml	4 ml

PLASMA:

When plasma is requested, select the tube specified and draw the FULL amount indicated. The appropriate color stopper is listed as a specimen requirement beside each test name or profile. Plasma is obtained from tubes with Lavender (L), or Blue (B) stoppers. After collection, mix the tube immediately by gently inverting 6-8 times to avoid clot formation. The approximate plasma yield for each size tube is as follows:

COLOR OF TUBE STOPPER	TUBE SIZE	APPROXIMATE AMOUNT OF PLASMA OBTAINED
Blue	2.7 ml 4.5 ml	1 ml 2 ml
Lavender	3 ml	1 ml

CLOTTED BLOOD:

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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When clotted blood is requested, draw a red top tube (R) and send to the laboratory unopened. Most clotted blood samples are for blood banking and require the patient's date of birth.

FROZEN SPECIMENS:

Serum should be separated and frozen immediately after centrifugation. Send the patient to the hospital laboratory collection center if a freezer is not accessible.

HEMOCONCENTRATION:

Hemoconcentration can falsely increase particular analytes, rendering specimens unsatisfactory for analysis. Please take the following precautions to prevent hemoconcentration, so the sample does not have to be recollected.

When collecting the sample, avoid the following:

- Application of tourniquet in excess of 1 minute.
- Performing venipuncture on children crying in equal to or in excess of five minutes. Have parent calm child; reattempt after child is in calm state for a duration of 30 minutes for non stat orders.
- Reference: Phlebotomy Essentials, Tankersley, 1998

HEMOLYSIS:

Hemolysis can falsely increase or decrease particular analytes, rendering the specimen unsatisfactory for analysis. Please take the following precautions to prevent hemolysis so the sample does not have to be recollected.

When collecting the sample, avoid the following:

Small gauge needles

- Forced expulsion of blood through needle while transferring to tube
 - Rigorous shaking of blood when inverting
 - Exposure of blood to below freezing conditions
- Avoid prolonged contact of the cells on the serum before separating the sample. Centrifuge for 10 minutes within one hour after collection.

URINE SPECIMEN:

Follow the specimen requirements for urine collection carefully. Generally, the preferred specimen for a urinalysis is a clean catch specimen. Refrigeration is necessary after collection (See instructions in English and Spanish).

For timed collections, mix the urine thoroughly before aliquoting it, and record the volume and time period of collection on the requisition. Special instruction sheets and containers containing certain preservatives are available for patients upon request.

STOOL SPECIMEN

Follow instructions in collecting stool specimens (See separate instructions in English and Spanish).

BODY FLUIDS:

When body fluids are submitted, place the fluid in the appropriate container ASAP, to avoid

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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deterioration of the cells. Cell counts require a lavender top (L) tube, chemistries require a red top tube (R), cultures require a sterile container, and cytology or non-gyn specimens require the addition of heparin prior to refrigeration.

Sputum

Give patient clear instructions. This will enhance the probability of obtaining a good sample of sputum rather than saliva. The specimen should be evaluated and recollected if sample appears to be saliva.

Routine Sputum Culture

- Early morning specimens are preferred since they are usually free of gross oral and nasal secretions. The hours of rest have allowed pooling of sputum in the patient's lungs
- Obtain the specimen when the cough is productive. This represents lung rather than Pharyngeal secretions
- Attempt to obtain sputum specimens before antibiotic therapy is initiated
- Do not obtain a sputum specimen immediately after a patient has eaten, chewed gum, smoked, brushed teeth, uses mouthwash, or does any activity that increases oral or nasal secretions
- If the patient is able, encourage rinsing mouth with fresh tap water to remove gross saliva before attempting to cough. (Do not rinse with tap water if Legionella or AFB cultures are ordered)
- If the patient has difficulty coughing, have the patient take a deep breath and hold it as long as possible. Then, while taking the next breath (inhaling), have the patient attempt a deep cough. During the period of holding the breath, the bronchial secretions pool and trigger the coughing mechanism
- Send all specimens to the lab immediately in sterile screw-cap containers. Many respiratory pathogens are fragile and may die or be overgrown with storage or delay in transport

Mycobacterium tuberculosis (TB) Sputum Culture

Submit three first morning expectorate sputum samples, collected on three different days. Refrigerate the samples. Gastric aspirates cannot be collected in an outpatient setting; the patient must not have been up and moved around before the procedure is performed. At least 3mL sputum is required for AFB cultures.

WOUNDS, ABSCESES, SINUS TRACT, SKIN LESIONS

For reliable culture results, good techniques for site preparation and specimen collection are essential. Tissue taken from the base or leading edge of the wound is more likely to recover viable clinically significant organisms than sampling of necrotic material.

- Anaerobic culture is limited to tissue and aspirated material in an anaerobic transport tube. See Microbiology Brochure for more information.

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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Examples of Common Specimen Source - How to Transport	
Specimen Type	Transport Device
Aspirate	Anaerobic transport tube or aerobic transport
Biopsies	For anaerobic culture, place in the anaerobic transport tube. Recommend at least 1 cm ³ for complete cultures. If anaerobic culture is not requested, the sample may be placed in a sterile tube with a few drops of sterile non-bacteriostatic saline to keep it moist.
Cervix	Appropriate for GC culture only. Use a Culturette®. swab. Transport immediately.
Cerebrospinal fluid	Collect in special CSF sterile plastic tube provided
Drainages	Use anaerobic transport tube. Use sterile tube or Culturette® swab.
Exudates	If swab, use Culturette®. If liquid and anaerobes requested, use anaerobic transport tube.
Fluids	Transport additional fluid (at least 1 mL) in a sterile tube and in an anaerobic transport tube if anaerobic culture is requested.
Fungus	Aspirate, biopsy, blood, body fluid, bronchoalveolar lavage, hair, nails, sinus, skin, sputum stool, urine or genital. See Fungus Collection Instructions. Collect 2mL or 1cc tissue in a sterile container; 50 mL body fluid, 5 mL aspirates. See Special Blood Culture Collection Section

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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Pus	If anaerobic culture is requested, inject aspirated pus into anaerobic transport tube and swab, use Culturette® (aerobic culture).
Skin scrapings	Place in sterile Petri dish.
Sputum, Routine	Obtain the specimen when the cough is productive, early morning is best. Collect in a sterile plastic container. Refrigerate.
Sputum for AFB	Submit three (3) first morning expectorate sputum samples, collected on three (3) different days. Refrigerate the samples. At least 3 mL sputum is required for AFB cultures.
Stool for culture	C&S Vial. Select bloody or mucous portions of the stool. Place sufficient volume into the Cary/Blair transport media to match the fill line. See Stool Collection Brochure.
Stool for ova and parasites	Place portions of the stool in Ova and Parasite kit sufficient to match the fill line. See Stool Collection Instructions
Tracheal aspirate (endotracheal aspirate)	Submit specimen in a sterile container with a screw cap lid.
Urine	Collect as clean catch in a sterile plastic container and aliquot into special Vacutainer Urine Culture transport tube with growth inhibitor (gray top). Refrigerate specimen if urine culture transport tube is not used. For urinalysis aliquot into a yellow top urine preservative transport tube.
Vaginal swab	For yeast culture. Collect in a Culturette® and send to the lab immediately. If bacterial vaginosis studies are requested, use a second swab to prepare slide or send second swab to lab. For group B strep screen, collect both vaginal and anal swab(s). Vaginal swabs are not appropriate for GC culture, only cervical swabs are acceptable for GC culture.
Wound	Collect on sterile aerobic swab using a culturette and transport promptly. If requesting a gram stain collect 2 Culturettes®. Only tissue or aspirated material is acceptable for anaerobic cultures. For anaerobic cultures, use an anaerobic transport device. See Microbiology Brochure for complete information

Policy Title	Specimen Collection and Handling	Policy #	LAB2370
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DIRECTED DONOR ORDERS:

Patients have the option of having family members or friends donate blood on their behalf, if their blood types are compatible and the surgery is scheduled at least 1 week in advance. Please note the following:

- Give the patient a completed Directed Donations request form. Call (831) 577-2000 for Directed Donor request forms. An example of the form is on the adjacent page.
- Instruct the patient to have a blood typing test and antibody screen by going to the hospital with their completed form.
- All potential donors must have a blood typing test also, which will be charged to the donor.
- Instruct the patient to call Red Cross Patient Services at (831) 577-2000.

Patients are reminded that this program is an option and does not imply a medical advantage. Blood is available to them at all times, and all blood must meet equally high standards.

AUTOLOGOUS ORDERS:

Give completed physician's request for Autologous Donation Form to patient, with instructions to call Red Cross Patient Services at (831) 577-2000 to set up a donation appointment. Additional autologous order forms can be requested by calling (831) 577-2000. An example of the form is on the adjacent page.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Lab Specimen Cancellation & Delays	Policy #	LAB2614
Responsible	Laboratory Director	Revised/Reviewed	09/22/2020 10/31/2022

I. PURPOSE

To define communication of uncollected lab specimens and delayed testing of lab specimens.

II. SCOPE AND APPLICABILITY

This policy applies to all lab orders.

III. POLICY

It is the policy of Watsonville Community Hospital that physician orders for lab tests will be followed.

Lab tests will only be ordered and/or cancelled with a physician's order.

Lab test delays will be communicated directly to the ordering physician or their designee (i.e., physician's office).

IV. DEFINITIONS

N/A

V. PROCEDURE

A. Uncollected lab specimens will only be cancelled with a physician order.

1. Uncollected or pending specimens will be communicated to the patient's nurse.
2. Lab personnel will not cancel a lab test without an order from the ordering physician.
3. Nursing personnel will not cancel a lab test without an order from the ordering physician.

B. Lab test delays, such as reference lab delays, will be communicated to the physician or designee.

C. Labs pending will be reviewed and communicated daily.

VI. REFERENCES

N/A

VII. STAKEHOLDERS

N/A

Policy Title	Specimen Rejection	Policy #	LAB2730
Responsible	Director of Laboratory	Revised/Reviewed	10/23/2020 10/31/2022

I. PURPOSE

To provide guidelines on specimen rejection.

II. POLICY

Proper specimen collection and handling are essential to obtaining valid, timely test results. All test requisitions and specimens must meet the defined criteria for identification, collection, volume, and testing in order to be processed. The lab will not process unlabeled, mislabeled, or misidentified specimens. When such a specimen is received, the laboratory will contact the ordering unit/clinic/physician's office. The nurse or physician will be informed that the specimen is improperly labeled. A new specimen should be obtained. If any criterion is not met, the attending physician, unit, or clinic will be notified immediately so that corrective action can be taken.

III. DEFINITIONS

N/A

IV. PROCEDURE

Clinical laboratory personnel reserve the right to reject samples that are unacceptable for analysis and request that a new specimen be obtained. This determination is a critical component of test result quality assurance.

1. Reject specimens for any one of the following reasons:
 - a. Patient identification on requisition doesn't match the specimen container.
 - b. Incomplete or no patient identification on specimen container.
 - c. Specimen submitted in broken, leaking or otherwise contaminated container.
 - d. Specimen collected in the wrong anticoagulant or wrong collection container.
 - e. Insufficient volume of specimen to perform testing.
 - f. Specimens improperly collected from IV sites
 - g. Others; please specify
2. Specimens of questionable nature may be referred to the Lab Director, if necessary, for a determination to be made.

Examples of unacceptable/sub-optimal samples would include:

CHEMISTRY

- a. Specimens for glucose which have not been centrifuged within 2 hours after time of collection.
- b. Hemolyzed specimens
- c. Specimens for infant bilirubin which have been exposed to light for prolonged periods.

Policy Title	Specimen Rejection	Policy #	LAB2730
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HEMATOLOGY/COAGULATION

- a. "Short draw" specimens for CBC, Hemogram, PT, APTT, etc.
- b. Clotted sample
- c. Body fluid specimens for cell counts which are clotted or contain clots.

URINALYSIS

Specimens which have been at room temperature for more than two hours since time of collection are generally not acceptable for microscopic analysis, culture, or nitrite test.

BLOOD BANK

- a. Specimens for crossmatch that are not COMPLETELY labeled with information prescribed in the operating instructions. NO unlabeled/mislabeled specimen for crossmatch will be accepted under any circumstances; all such specimens are to be redrawn.
- b. Hemolyzed specimens. Any degree of hemolysis is unacceptable and must be rejected. Except for occasional instances where using hemolyzed specimen is unavoidable, i.e., OR, ONC and patients with AIHA, or any clinical conditions causing hemolysis as a result of in vivo antigen-antibody reaction. Document in the Error/Variance Log if hemolyzed specimen is used.
- c. No R# assigned for Type & Screen with Crossmatch

MICROBIOLOGY

- a. Foley Catheter tip for culture
- b. Unpreserved stool cultures of more than 2 hours
- c. Sputum specimen, >2 hrs.

SPECIMEN REJECTION PROTOCOL

- a. Inpatients
 - i. Call the inpatient unit.
 - ii. Explain the problem to a nurse and request a new specimen be collected ASAP.
 - iii. Cancel the request in the HMS system.
- b. Outpatients/Drop-off Samples
 - i. Cancel the original order indicating the reason for specimen rejection.
 - ii. Call the clinic/physician's office and explain the problem.
 - iii. Re-call the patient, explaining the reason a new sample is needed.
 - iv. Document the disposition of every specimen that meets one or more criteria for rejection using the "Specimen Rejection Log". Always document even mildly questionable situations.
- c. Unrecoverable/Difficult Specimens -
 - i. In cases where specimens are difficult to re-collect (CSF, surgical tissues, cytology, and body fluids) and could seriously compromise patient care or impose undue risk, call the attending provider and

Policy Title	Specimen Rejection	Policy #	LAB2730
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explain the problem. Ask the provider if he/she wants the requested test(s) performed on the sub-optimal specimen.

- ii. If the provider requests you to perform the test, document this request in the HMS under "Comment" field". Include the date/time and name of the person who authorized performance of the test.
- iii. However, the first priority is to the patient. Do not accept a specimen that could potentially cause generation of erroneous medical data and thereby result in inappropriate treatment action.
- d. Document Specimen Rejection in HMS
 - i. Go to F3 Work with Orders and pull up the order. Then use R (Reject) to cancel the specimen.
 - ii. F4 for the reason.
 - iii. You will then have the option of **Reject and Reorder** or **Reject and Cancel**.

3.a Use Reject and Reorder and you will get a new requisition automatically. The specimen will be drawn and received on the new order without having to comment.

3.b Use Reject and Cancel if specimen does not recollection.

V. REFERENCES

Richael JL, Naples MF. Creating a workable specimen rejection policy. Medical Laboratory Observer Mar 1995; 27 (3):37-42.

VI. STAKEHOLDERS

N/A

Policy Title	Emergency Product Issue to Unknown Patient in Wyngate	Policy #	LAB2734
Responsible	Laboratory Director/VP, Ancillary Services	Revised/Reviewed	09/22/2020 10/17/2022

I. PURPOSE

This procedure is for Emergency product issue when patient is unknown or patient does not exist in Wyngate.

II. POLICY

- Do not delay transfusion waiting on the blood and blood.
- Positive patient identification is the most critical control point to ensure a safe transfusion.
- Two individuals must confirm identification of donor unit and patient information at the time of component issue and at the time of transfusion.
- Good communication is vital and facilitates appropriate blood product provision for the patient.

III. DEFINITIONS

N/A

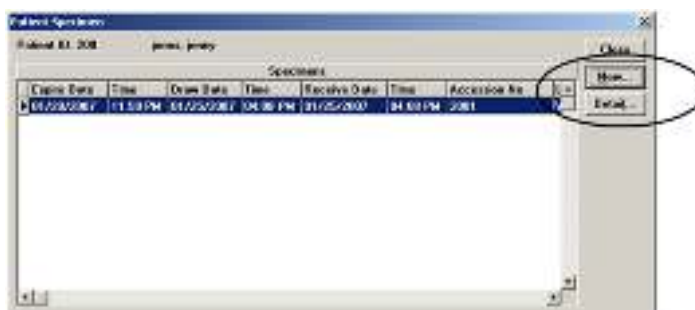
IV. PROCEDURE

From the Patient/Order Profile:

1. Select *PRODUCT* ☐ *EMERGENCY ISSUE* ☐ *EMERGENCY PRODUCT ISSUE– UNKNOWN PATIENT*.
2. On the *Emergency Product Issue - Unknown Patient* window enter a **patient name** or select the *Generate* button to record a system generated disaster name and a Safe Trace Tx patient ID.
3. Enter a Service Provider, Issue Location and Released to data.
4. Enter the unit information using the *Manual* enter button.
5. Select *Accept*. The unit information will now be transferred to the *Products to Issue* grid.
6. Press *OK*. The system saves the information, prints a *Product ID tag* and closes the window.
7. The system automatically generates a Patient Profile and an emergency Order for the Product. A specimen must be created and a Type and Screen and Crossmatch must be added to that order.
8. Open the order with the issued RBC on it. *FILE* ☐ *OPEN* ☐ *ORDER*. Use the Patient ID # to search and select the appropriate order.
9. With the Order Profile window open: Select *ORDERS* ☐ *CHANGE STATUS TO ORDERED*. The order Status updates from completed to Ordered and the order may now be edited.

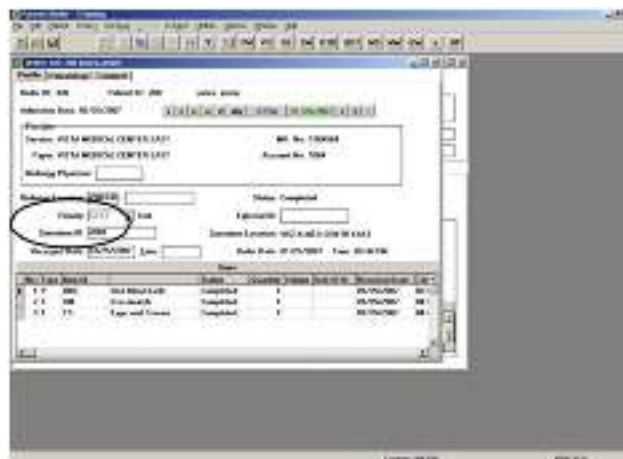
Policy Title	Emergency Product Issue to Unknown Patient in Wyndgate	Policy #	LAB2734
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10. Create a new specimen for the patient. Press the **Specimen Expiration data field** on the Patient-At-A-glance Bar. This will open the *Patient Specimen* window. Create a new specimen. Use the Lab Fusion number as the Accession number or if no orders have been placed yet, generate a Wyndgate Accession number by pressing the *Generate* button.



11. On the Order screen, right click in the specimen ID field. Press Query. Select the specimen number.

DO NOT UPDATE PATIENT'S INFORMATION UNTIL YOU HAVE A SPECIMEN IN WYNDGATE!!!



12. Add a Crossmatch order
 - a. Select **ORDERS** ☐ **ITEM** ☐ **TEST BATTERY**. The *Order Item TestBattery* window will now be displayed.
 - b. Select the appropriate crossmatch.
 - c. Press **OK**.

Policy Title	Emergency Product Issue to Unknown Patient in Wyngate	Policy #	LAB2734
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Test Battery	
Test Battery ID	XM Crossmatch

Test Battery Test	
Test ID	XM IS Crossmatch
Test ID	XM ISS Crossmatch
Test ID	XM PW2 Crossmatch
Test ID	XM NOEN Crossmatch

13. Add a Type and Screen order.

Add a row to the Items grid and enter **Type (T)**, **Item ID (TS)** and **Quantity**.

Test Battery	
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Test Battery Test	
Test ID	XM ISS Crossmatch
Test ID	XM PW2 Crossmatch

14. Press **Save** icon from Tool bar.

15. Enter results following the Entering Results procedure.

UPDATING EMERGENCY ISSUE

The system generated Patient Profile for the unknown patient is used to record the patient's known information. This must be done before the specimen is created or after all tests are completed.

From the Patient/Order module:

1. Open the Patient Profile. Select **FILE** ☐ **OPEN** ☐ **PATIENT**. The Open Patient window will now be displayed.

Policy Title	Emergency Product Issue to Unknown Patient in Wyngate	Policy #	LAB2734
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2. Enter the Patient's search criteria. Select Query. Matching patient records will be displayed in the Patients grid for visual review.
3. Select the correct patient from the Patients grid and select the OK button. The Corresponding Patient Profile window will be displayed.
4. The unknown patient's Patient Profile window will display the patient information that was recorded to the Emergency Product Issue – Unknown Patient window.
5. Update patient information on the Patient Profile window by selecting a data field enclosed in a box and enter the new information. At a minimum the patient's gender, medical record number and account number must be recorded.
6. Select the Save icon to update the database.
7. The patient's Specimen will become unavailable for use following this update. The specimen must be returned to an available status before further testing can be done. (See the Returning Specimen to Available Status procedure)

I. REFERENCES

N/A

II. STAKEHOLDERS

N/A

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
Responsible	VP, Ancillary Services	Revised/Reviewed	09/2020 10/18/2022

I. **PURPOSE**

To ensure that the Watsonville Community Hospital has the ability to produce accurate, reliable, and timely results. That lab services provided are safe, effective, and appropriate and are patient- centered.

II. **RATIONALE**

The Patient Protection and Affordable Care Act of 2010 changed the laboratory landscape, and as a result, quality has become more relevant than ever. The new impetus is for laboratories to think about value instead of volume, which translates into a need to have leaner processes, work more efficiently, eliminate redundant testing, and work cooperatively with the rest of the clinical patient management team.

III. **DEFINITIONS**

■ **Quality Management System (QMS)** is an overarching system of specific policies and procedures to address all the activities within a laboratory. A QMS goes beyond Quality Control (QC) and Quality Assurance (QA), and it entails looking at the laboratory as an all-inclusive system, ensuring there are guidelines for addressing activities in all areas. A comprehensive QMS can help a laboratory ensure that all activities are monitored and evaluated, and results are accurate and reliable. In quality management, the focus the quality efforts from detection to prevention.

■ **Quality Control (QC)** is to provide feedback to operational staff about the state of a process that is in progress. QC tells staff whether to continue (everything is acceptable) or to stop until a problem has been resolved (something is found to be out of control).

■ **Quality Assurance (QA)** are activities, such as the development of documents like standard operating procedures (SOPs), to ensure consistent and correct performance of processes, training of personnel, and qualification of materials and equipment. Quality assurance activities also include retrospective reviews and analyses of operational performance data to determine whether the overall process is in a state of control and to detect shifts or trends that require attention. Quality assurance provides information that can be used in setting priorities for process improvement.

IV. **QUALITY MANAGEMENT SYSTEM COMPONENTS**

1. Organization and leadership
2. Customer focus
3. Facilities, work environment, and safety

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
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4. Human resources
5. Suppliers and materials management
6. Equipment management
7. Process management
8. Documents and records.
9. Information management.
10. Monitoring and assessment.
11. Process improvement

ORGANIZATION AND LEADERSHIP
Clinical Laboratory Organizational Chart

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
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name & MRN). On the computer-generated label, collector should put their initials, date and time of collection.

***** Refer to Specimen Labeling, Receipt, Collection and Transportation Policy.**

1.2.2 To maintain the integrity and accuracy of results, specimen must be collected using the required container and submitted to the laboratory without any signs of being compromised. If the specimen received is not at the proper requirement and compromised, the CLS has the right to reject the sample and request for recollection.

***** Refer to Specimen Rejection Policy**

1.2.3 For accurate results, specimen collection and handling must be followed at all times. Refer to **Specimen Collection and Handling Policy**.

1.3 Quality Control

- 1.3.1 To ensure that equipment and existing methods are properly functioning and to ensure the accuracy and precision of patient results, quality control is performed everyday at a various time interval in all sections in the lab.
- 1.3.2 Quality control material will be run and recorded by staff assigned to each department according to the schedule established by the Section Head. Corrective action will be recorded if necessary. **Do not report patient results if QC is unacceptable.**
- 1.3.3 Quality control review is performed monthly by the Section Head or designee and approved by the Laboratory Director.

*****Refer to Laboratory Quality Control Policy**

1.4 Reagents/Control Materials

- 1.4.1 To ensure the specificity, reactivity and potency of reagents and control materials used in the laboratory, follow storage protocol based from the manufacturer's recommendation. Reagents and control materials should be stored in a monitored refrigerator and checked for any signs of deterioration on a daily basis. Room temperature reagents should be stored properly and room temperature should be monitored daily.
- 1.4.2 Reagents should be dated upon opening.
- 1.4.3 Unopened controls are stable until expiration when stored according to the manufacturer's recommendation. Opened controls must be dated upon opening and expiration date must be indicated depending on the manufacturer's recommendation.

1.5 Equipment

- 1.5.1 Equipment, instruments and measuring devices are considered critical when used in patient specimen testing. Therefore, calibration, monitoring and maintenance must be performed at established intervals (Refer to "Laboratory Instrument Maintenance" policy).
- 1.5.2 Daily, weekly and monthly maintenance activities must be followed. Maintenance compliance is monitored by the Section Head or designee.

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
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- 1.5.3 New instrument must be validated and approved for use by the Laboratory Director prior to implementation.

***** Refer to Laboratory Instrument Maintenance Policy, Method Validation Prior to Implementation**

1.6 Linearity/Calibration Verification/Correlation Studies

- 1.6.1 Calibration verification is performed every six months and whenever the following events occur;
- 1.6.1.1 A complete change of reagents for a procedure introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by the reagent lot number.
 - 1.6.1.2 Major preventive maintenance is performed, or critical parts are replaced that may influence test performance.
 - 1.6.1.3 Quality control results indicate that there may be a problem with the test system.
 - 1.6.1.4 Environmental change occurs, including instrument relocation.
 - 1.6.1.5 An instrument has been replaced.
 - 1.6.1.6 Quality control materials reflect an unusual trend or shift or are outside the laboratory's acceptable limits, and other means of assessing and correcting the problem failed to identify and correct the issue.

1.7 Proficiency Testing

- 1.7.1 To comply with CLIA regulations, testing of proficiency materials will be performed by licensed Clinical Laboratory Scientists in the same manner as patient samples.
- 1.7.2 Proficiency testing material is supplied through vendors that have been approved through CLIA. The samples are tested in the same manner as patient testing, by a variety of staff members on a rotation basis. Remedial actions and a thorough investigation are taken when results are not within acceptable limits.
- 1.7.3 Proficiency Testing results are also submitted quarterly to the Quality Coordinating Council for review.

*****Refer to Proficiency Testing Program Policy**

1.8 Documentation

- 1.8.1 A sound documentation is essential in maintaining a high standard quality care. Documentation of quality control, proficiency testing, temperature monitoring and maintenance must be well-documented.
- 1.8.2 Patient's results review or surveillance must be done on a daily basis and must be documented. As errors are discovered, investigation and corrective action must be performed. Identification and resolution of the problem must be developed by the Lab. Director to prevent recurrence.

***** Refer to Result Review Report Policy**

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
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- 1.8.3 In order for the records to be accessible when needed, a record retention policy is developed to comply with the accrediting, state and federal agencies.

*****Refer to Record Retention Policy**

1.9 Laboratory Operation and Personnel

- 1.9.1 The in-patient laboratory is open 24 hours a day/7 days a week. Outpatient laboratory services are available Monday through Friday from 7:30 a.m. to 5 p.m.
- 1.9.2 **Testing personnel and general supervisors** consist of California Licensed Clinical Laboratory Scientists who perform a variety of tests, many of which, according to Guidelines established by CLIA, are of high complexity. The Clinical Laboratory Scientist analyzes data, makes judgments based on that data and takes appropriate action. Additionally, they are available to solve problems related to the collection and processing of biological specimens for analysis.
- 1.9.3** Certified Phlebotomy Technicians perform a variety of tasks necessary for the acquisition, transport and processing of laboratory specimens. These tasks include phlebotomy on geriatric, adult, adolescent, pediatric and infant patients, specimen processing, data entry, results retrieval and much more. **No testing performed by the CPTs.**

***** Refer to Laboratory Plan for Providing Patient Care Policy, Laboratory Supervision Policy.**

- 1.9.4 Staff competency is initially determined during new employee training. Competency is assessed for new employees approximately six months after hire and then annually thereafter.

***** Refer to New Laboratory Employee Orientation Policy**

- 1.9.5 Continuing education is encouraged and opportunities are provided in- house and at off-site locations.

1.10 Supplier Issues

- 1.10.1 All critical supplies are received on the loading dock of Watsonville Community Hospital's Materials Management Department. The packing slip is compared to the original P.O. for accuracy of information shipped. The supplies are then brought to the Laboratory. Any discrepancies in the packing slip and P.O. are brought to the attention of the Lab Admin Director or the designee.
- 1.10.2 The Laboratory staff is responsible for distribution and storage of supplies once in the Laboratory. Supplies, components and equipment not conforming to expected specifications are quarantined pending investigation and documented on Supplier/Vendor Variance Log. (Check log)

1.11 Laboratory Quality Assessment

Policy Title	Laboratory Quality Management System Assurance Plan Quality Management and Quality Control Plan	Policy #	LAB2830
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1.11.1 The Laboratory Quality Assessment Plan is developed to monitor performance improvement of the clinical laboratory. The scope of the plan represents all disciplines across the laboratory workflow; preanalytical, analytical and post-analytical. The LQAP monitors and evaluates the quality and appropriateness of patient care rendered by the laboratory. The performance is measured through data collection and data are used in assessing the laboratory's performance improvement. Data collection and analysis are performed and submitted to the Laboratory Director and QCC for approval and recommendation.

*****Refer to Laboratory Quality Assessment Plan**

VI. REFERENCES

CLIA '88, Comprehensive Accreditation Manual for Laboratory
and POCT (TJC)

VII. STAKEHOLDERS

N/A

Policy Title	Gastrocult (Gastric Occult Blood and PH Test)	Policy #	LAB2905
Responsible	Laboratory Director	Revised/Reviewed	09/2020 12/15/2022

I. INTENDED USE

Gastrocult* is a rapid screening test designed for detecting the presence of occult blood and determining the pH of gastric aspirate or vomitus. It is a useful aid in the diagnosis and management of various gastric condition. The kit contains easy to use paperboard slides consisting of standardized, high quality filter paper treated with natural guaiac resin. Application of Gastrocult Developer (a buffered, stabilized hydrogen peroxide solution) causes a peroxidase-like reaction that turns the test paper blue if blood is present

II. PRINCIPLE

The Gastrocult test for blood is based on the reaction of alpha guaiaconic acid with hydrogen peroxide in the presence of heme to produce a highly conjugated blue quinone compound. The Gastrocult pH test is based on changes in the color of dyes due to changes in hydrogen ion concentration.

III. PURPOSE:

Gastrocult is a qualitative screening method for detecting the presence of occult blood and determining the pH of gastric aspirate or vomitus. Results cannot be considered conclusive evidence of presence or absence of gastrointestinal bleeding or pathology.

IV. SCOPE OF PRACTICE

Gastric occult blood and pH testing may be performed the Clinical Lab Scientist.

LIMITATIONS

As with any occult blood test, the results of the Gastrocult test cannot be considered conclusive evidence of the presence of upper gastrointestinal bleeding or pathology. Gastrocult tests are designed as an aid to diagnosis, and are not intended to replace other diagnostic procedures such as X-ray studies or Endoscopy. Gastrocult test results should only be used in conjunction with other information relevant to the clinical status of the patient. A positive test result may suggest the need for more careful monitoring of the patient.

V. SPECIMEN COLLECTION (By nurses or MDs)

Either gastric aspirate obtained by nasogastric intubation or vomitus is an appropriate sample for use with the Gastrocult test. Prior to collecting the patient's sample, the patient's identity must be verified by looking at the armband. Sample may be applied by using the applicators provided in Page 2 of 5 the kit, or by any other method whereby a small amount of test material is applied to the reaction areas.

Specimen Type

Small volumes (several drops) are adequate for testing.

Gastric aspirate obtained by nasogastric intubation or vomitus are appropriate samples.

Fecal specimens are not recommended.

Handling Conditions

- Sample can be applied using available applicators, or by any method of applying one drop to both the occult blood and pH reaction sites.
- Samples must be tested for pH immediately after collection.
- The Gastrocult blood test area may be developed immediately or up to 4 days after sample application; store at controlled room temperature 15- 300C.

Policy Title	Gastrocult (Gastric Occult Blood and PH Test)	Policy #	LAB2905
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- Samples for blood testing may be stored, prior to application, in a clean sealed container for 24 hours at controlled room temperature 15-30 °C, or 5 days refrigerated at 2-8 °C.

VI. REAGENTS AND SUPPLIES

- Beckman Coulter Gastrocult slides (test cards) containing guaiac paper
- Beckman Coulter Gastrocult developer (stabilized aqueous solution.
- <2.9% hydrogen peroxide, <33% denatured ethanol in citrate buffer)

VII. REAGENT STORAGE AND STABILITY

- Store slides (test cards) at controlled room temperature 15° - 30°C (59 to 86°F).
- Do not refrigerate or freeze.
- Protect slides and developer from excessive heat and light.
- Slides must be sealed inside provided wrapper until ready for use. Protect from open air.
- Do not store test cards or developer near volatile chemicals.
- Gastrocult slides and developer, stored as recommended, are stable until printed expiration dates, if quality control (QC) is acceptable.
- **All reagents must be labeled with staff initials, and date opened.**

VIII. PRECAUTIONS

- Because this test is visually read and requires color differentiation, it should not be interpreted by the visually impaired.
- Gastrocult Developer should be protected from heat and the bottle kept tightly capped when not in use. It is flammable and subject to evaporation. It is also an irritant. Avoid contact with skin.
- **DO NOT USE IN EYES.** Should contact occur, rinse properly with water.

IX. PROCEDURE

1. Collect gastric sample
2. Open slide
3. Apply one drop of sample to slide pH test area
4. Apply one drop of sample to slide occult blood test area\
5. Determine pH of sample within 30 seconds, by visual comparison of test area to pH color comparator on the slide.
6. Apply two drops of Gastrocult Developer directly over sample in occult blood test area. Interpret result within 60 seconds.
7. Add one drop of Gastrocult Developer between the positive and negative
8. Interpret results within 60 seconds. If the slide and developer are functional, blue color will appear in the positive area, and the negative area will remain colorless. *If the Performance Monitor areas do not react as expected after applying the developer, regard patient results as invalid. Follow the corrective action steps outlined below.*

X. CORRECTIVE ACTION

1. Do not report the patient result.
2. Check expiration dates of the guaiac slides and developer.
3. Review the procedure.
4. Repeat control monitors with a new slide and freshly opened developer.
5. If control monitors perform correctly on repeat, discard old vial of developer.
6. Using a new slide repeat patient test and controls. Report patient results.
7. Record all control results on the QC log and note any corrective action take, i.e. opened new bottle of developer
8. If the controls do not perform correctly on repeat, call the manufacturer of Gastrocult, Beckman Coulter-800-877-6242

Perform quality control of the pH test portion of the Gastrocult slide using colorless buffered reference standard, standardized against the National Institute of Standard and technology. Use two levels of the standard:

- a. **Neutral-pH 7.0**

Policy Title	Gastrocult (Gastric Occult Blood and PH Test)	Policy #	LAB2905
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b. Acid-pH 2.0-4.0

c. Reference range: 1.5—3.5

XI.

QUALITY CONTROL

1. Monitor Reagents and Storage

- Date all slide boxes and Developer bottles when opened. All slides, developer, and buffers are stable until the manufacturer's expiration date
- Gastrocult Developer is stored tightly capped at room temperature (15-30 degrees C or 59-86 degrees F)
- Gastrocult Developer is stored tightly capped at room temperature
- pH buffers (pH 2 and pH 7) are stored tightly capped at room temperature

2. Quality Control Frequency

- **Weekly** on each opened box of Gastrocult slides and bottle of developer
- **Initially** when opening a new box of slides, developer or pH buffer
- **After each patient test.** For occult blood QC (Performance Monitor)

3. Quality Control-Performance Monitor

To test the function and stability of the guaiac paper and developer, a positive and negative occult blood Performance Monitor is built into each Gastrocult test card.

- Record the lot number and expiration dates of the Gastrocult slides and Developer on the Gastrocult QC log sheet, along with the date, time and operator initials
- Open the slide and apply 1 drop of Gastrocult Developer to the area between the positive and negative
- Interpret the result within 10 seconds
 - No color should appear in the "negative" location
 - A blue color should appear in the "positive" location
 - Document results on the Gastrocult QC log sheet and sign
 - Document any QC failures and corrective actions on the QC log sheet.
 - Record the date and operator initials on the QC label attached to the Gastrocult slide box
- Quality Control - pH
- Record the lot number and the expiration dates of the pH buffers on the QC log sheet
- Open two (2) Gastrocult slides
 - Label one slide as pH 2 and the second slide as pH 7
 - Apply one drop of pH 2 buffer to the pH test circle of the first slide labeled pH 2, then apply one drop of pH 7 buffer to the pH test circle of the second slide
 - Within 30 seconds, visually compare the pH test area on the slide to the pH color chart comparator.
 - Record the actual number value of the pH QC result on the Gastrocult QC log sheet.
 - Document any QC failures and corrective actions on the Gastrocult QC log sheet

XII. RESULTS

The pH value of the gastric sample is interpreted as the closest color match to a numerical value within the comparator range.

Blue color formed after Gastrocult developer is applied to the occult blood test area indicates the presence of blood in the sample and should be reported as **"Positive"**.

NOTE: Some gastric samples may be highly colored and appear as blue or green on the test area. Test results should only be regarded as positive if additional blue is formed after Gastrocult Developer is added.

PH test results are reported/recorded in whole numbers of 1 through 7+.

Occult blood test results are reported/recorded as "Positive" or "Negative" for gastric occult blood.

XIII. DOCUMENTATION

The following information is required to be documented with patient results in the permanent

Policy Title	Gastrocult (Gastric Occult Blood and PH Test)	Policy #	LAB2905
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medical record:

- Date and Time of patient testing
- Test card lot number and expiration date
- Developer lot number and expiration date
- Results of occult blood positive and negative performance monitor
- Identification of staff performing testing.

XIV. PROCEDURE NOTES

If the sample is applied in such a way that it contacts the Performance Monitor areas, the negative Performance Monitor area may appear positive. This should be avoided. Any blue originating from the Performance Monitor areas should be ignored when reading the specimen test results. Neither the intensity nor the shade of the blue from the positive Performance Monitor area should be used as reference for the appearance of positive test results. .

DO NOT use Gastrocult slides or developer to test for fecal occult blood.

DO NOT use Hemoccult slides or developer to test for gastric occult blood.

XV. REFERENCES

1. Gastrocult Package Insert #B 461780, Beckman Coulter, Inc., Rev. September 2015

XV. STAKEHOLDERS

N/A

Policy Title	Fungus	Policy #	LAB131025
Responsible	Laboratory	Revised/Reviewed	12/2020 10/18/2022

I. PURPOSE/PRINCIPLE

Fungi are significant, sometimes overlooked, human pathogens. Infections range in severity from merely cosmetic to life threatening.

A wide variety of fungal species may be encountered in clinical specimens. Isolation and differentiation of fungi by growth on agar plates provides an optimum of sensitivity and specificity for the diagnosis of fungal diseases. Culture data must always be evaluated in terms of the patient's clinical condition

II. POLICY

Specimens submitted for full fungal cultures will be sent to a reference lab. Mold isolates that grow on routine cultures may need to be sent out for identification. Yeast isolates can be identified in this lab. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS N/A

IV. STORAGE N/A

V. SPECIMEN

Since fungal elements are generally found in fewer numbers than are found in bacterial infections, larger sample sizes should be used. This means that transport media swabs are not usually recommended. Instead fresh body fluids and tissue of at least 1ml should be sent in sterile containers. Fungal elements can survive in a moist environment for extended periods without transport media. All specimens must be fully labeled with the identity of the patient and the source of the specimen.

VI. QUALITY CONTROL:

All fungal culture plates are QC tested by the manufacturer. QC vouchers should be initialed after the inspection of each shipment and stored in the Media QC Voucher binder.

VII. PROCEDURE

Plates growing filamentous fungi should not be opened. Any plates growing filamentous fungi should be sealed with gas-permeable tape (para-film) or shrink wrap to prevent possible exposure.

1. Molds growing on routine cultures may be significant and can be sent out to a reference laboratory for identification. Direct communication with the doctor can aid in determining the need for identification of the mold. Molds growing on plates can be to the reference laboratory. Contact the reference laboratory prior to submitting plate to make sure a sealed plate is acceptable. Do not attempt to transfer part of the mold colony to another medium for transport.

Policy Title	Fungus	Policy #	LAB131025
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2. The Vitek Yeast ID card can be used to identify yeast growing in the culture. See the Vitek ID and Susceptibility policy for further instruction.

VIII. INTERPRETATION

Whether a mold should be identified to the genus or species level depends on the clinical status of the patient and the site from which the organism was isolated. The isolation of molds should be considered significant unless there is clear evidence that the mold is a contaminant. The physician must be consulted to determine if further work up is warranted.

IX. REPORTING RESULTS

Yeast isolates may be identified to the species level with the Vitek Yeast ID card. Yeasts are common commensals or contaminants in many clinical specimens. All yeast isolated from sterile sites like blood or CSF should be speciated. Yeast isolated from nonsterile sites such as urine specimens need be speciated only when found in large numbers. The correct identification of clinically significant yeast is important because some yeast have known antibiotic resistance patterns.

A yeast colony observed with "feet" and gram stain result of budding yeast cells may be given a presumptive ID of *Candida albicans*. Definitive yeast ID can only be reported when a Vitek Yeast ID card has been performed.

X. LIMITATIONS

- The failure to isolate the causative fungi from an infected patient is dependent on many factors. The most notable factors are the relative scarceness of fungi in clinical specimens and the quality of the specimens submitted. Repeat cultures may be necessary to effectively rule out the presence of fungal pathogens.
- All mycology results should be evaluated in the context of the patient's clinical condition necessitating good communication between the mycologist and physician.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

N/A

Policy Title	Carba NP	Policy #	LAB131057
Responsible	Laboratory Director	Revised/Reviewed	04/28/2020 10/18/2022

I. PURPOSE/PRINCIPLE

Carbapenemases are β -lactamases that are capable of inactivating most existing β -lactams. Their spread among Gram-negative bacilli is a major public health concern due to the extensive resistance they confer and their rapid global dissemination. The acquisition of a Carbapenemases-producing strain by a patient represents a mortality risk factor. For these reasons, their rapid detection is of utmost importance for the determination of appropriate schemes for reducing the risk of primary and secondary infection, and the implementation of infection control measures in intensive care units.

Carba NP is a phenotypic (colorimetric) *in vitro* diagnostic test for the qualitative detection of carbapenemase enzymes in *Enterobacteriaceae* and *Pseudomonas aeruginosa* colonies that have elevated MIC values to any carbapenem. Carba NP is performed on pure colonies grown on non-selective sheep blood agar culture media. Carba NP is not intended to guide or monitor the treatment for these bacterial infections. A negative result does not preclude the presence of carbapenemase enzymes. The ability of the Carba NP to detect carbapenemases enzymes encoded by genetic marker other than KPC, NDM, OXA-48, VIM and IMP has not been established.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Strips, incubation lids, stirring sticks
Ampules of API Suspension Medium
Two-colored (black and white) support

IV. STORAGE

Strips should be stored at 2-8°C in the dark until the expiry date indicated on the packaging. After opening the kit, check that the ampules are intact. If any are broken, the kit must be disposed of.

V. SPECIMEN

Routine Subculture / Incubation
Enterobacteriaceae or *Pseudomonas aeruginosa* with elevated carbapenem MIC to be tested must be isolated on a BAP media.

VI. QUALITY CONTROL

QC to be performed with each specimen tested. Record results on Carba NP QC Form.

Positive organism: *Klebsiella pneumoniae* ATCC 1705

Negative organism: *Klebsiella pneumoniae* ATCC 1706 (may look mixed on plate)

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

Policy Title	Carba NP	Policy #	LAB131057
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VII. PROCEDURE

Open the ampule

- Place the ampule in the ampule protector.
- Hold the protected ampule in one hand in a vertical position (white plastic cap uppermost).
- Press the cap down as far as possible.
- Position the thumb tip on the striated part of the cap and press forward to snap off the top of the ampule.
- Take the ampule out of the ampule protector and put the protector aside for subsequent use.

Preparation of the strip

- Remove the strip from its packaging.
- Write the specimen reference numbers on the strip on the plastic extension on the bottom of the strip.

Preparation of the test (Refer to Figure 1 for these steps)

- Open an ampule of API Suspension Medium (2 mL) by following the ampule opening steps as indicated in the paragraph above.
- Dispense 100 µL into each of the wells A, B and C.
- Place an incubation lid on the strip.
- Leave at room temperature (15-25°C) for 4-10 minutes and then,
- Gently mix the contents of well B using a stick provided in the kit.

CAUTION: *Do not use saline solution to rehydrate wells A, B or C.*

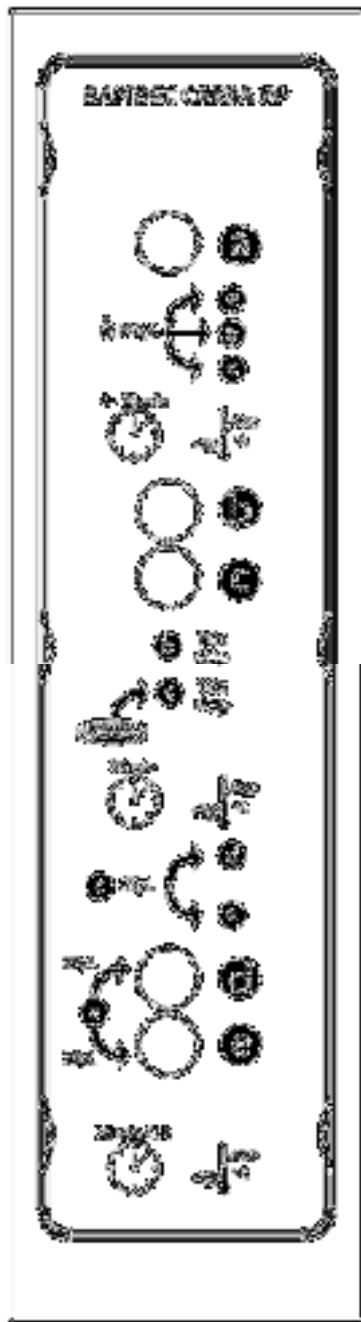
Preparation of the inoculum and bacterial lysis

- Place the strip on the two-colored (black and white) support. Position wells B and C on the black background to facilitate comparison of turbidities.
- With the end of a new stick, pick up several colonies of the same morphology taking care not to pick up any agar fragments.
- Deposit the contents of the stick in well C and mix. Repeat this step several times until a turbidity equivalent to that of well B is obtained so that the bottom of the wells must not be visible in the black background. The suspension in well C must be perfectly homogeneous, with no aggregates.
- Place the lid on and leave at room temperature (15-25°C) for 30 minutes.

Testing Procedure

- Use a micropipette to transfer 25 µL from well C to wells D and E then.
- Use a new tip to transfer 25 µL from well A to wells D and E.
- Place the incubation lid on and incubate the strip for 30 minutes at 33-38°C.

Policy Title	Carba NP	Policy #	LAB131057
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VIII. INTERPRETATION

CAUTION: Positive tests results are frequently obtained at 30 minutes of incubation. Re-incubate if negative or doubtful. After 30 minutes, there is a risk that a positive result may change back to a negative. Therefore, it is imperative to perform the initial reading at 30 minutes of incubation.

Reading the strip

- Place the strip on the two-colored (black and white) support. Position wells D and C on the white background to facilitate reading.
- Remove the incubation lid. Reading is performed by comparing the colors in wells D and C, ensuring that the strip is firmly flatten against the two-colored (black and white) support.

Policy Title	Carba NP	Policy #	LAB131057
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Perform the initial reading

In case of a negative or doubtful reaction, re-incubate the strip for an additional 1 hour 30 minutes and perform a final reading. The total test incubation time must not exceed 2 hours.

A test is positive when a significant variation in color is observed between the two wells.

Control well d	Test well e	Interpretation
red	red	Negative (absence of carbapenemase)
orange	orange	
red	yellow, light orange, orange, dark orange	Positive (presence of carbapenemase)
orange	yellow	
any color other than red or orange	Not applicable	*Uninterpretable
orange	red	

* An Uninterpretable result should be retested. If the retest yields an uninterpretable result, consider testing with an alternate method to determine carbapenemase status of the isolate.

IX. REPORTING RESULTS

Record result in LIS internal comments as Carba NP positive or negative using the CARBA canned comment. This result may be reported in the external comments using the canned comment CRE.

X. LIMITATIONS

- The performance of the Carba NP assay for detection of carbapenemases enzymes encoded by genetic markers other than KPC, NDM, OXA-48, VIM and/or IMP has not been established. In addition, Carba NP results may be influenced by the local epidemiology regarding genetic markers of resistance, i.e., depending on the local distribution/prevalence of different carbapenemase genetic markers, and more false negative results may occur. Conduct alternative testing if negative results are obtained and carbapenemase enzyme production is suspected based on local epidemiology.
- Carba NP testing should be used as an adjunct to other laboratory test(s) such as antimicrobial susceptibility testing.
- The performance of the Carba NP test with bacteria other than *Enterobacteriaceae* and *Pseudomonas aeruginosa* has not been evaluated. Organism identification and elevated carbapenem MICs should be determined prior to testing on the Carba NP.
- Proteus* species, *Providencia* species, *Morganella* species may have elevated imipenem MICs due to intrinsic resistance mechanisms. *Pseudomonas aeruginosa* has been shown to exhibit resistance to ertapenem due to intrinsic resistance mechanisms.
- The detection of OXA variants other than OXA-48 has not been evaluated sufficiently in the study.
- Hyper mucoid colonies may lead to false positive or false negative results and should not be tested by the Carba NP test. A hyper mucoid colony tends to stretch itself to form a continuous viscous filament > 5 mm in length when picked up from an agar plate using a bacteriology loop/needle.
- Agar media containing pH indicator for colony color differentiation (e.g., Bromocresol Purple, MacConkey, Cysteine Lactose Electrolyte-Deficient, etc.) are not compatible with the Carba NP and require sub culturing growth/biomass on a sheep blood agar for testing.
- The performance of Carba NP has been evaluated for sub culturing growth on 5% sheep blood agar incubated for 18- 24 hours (Routine procedure) and 4-5 hours (Short Incubation procedure)

Policy Title	Carba NP	Policy #	LAB131057
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only. The performance with other culture media has not been evaluated and is therefore unknown.

- The performance of the Carba NP test when testing *Enterobacteriaceae* and *Pseudomonas aeruginosa* containing OXA-181, OXA-232, SME, GIM, SPM, and IMI carbapenemase enzymes has not been established due to the low number of positive isolates available using the Composite Reference Method.

XI. REFERENCES

- Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
- RAPIDEC CARBA NP Package Insert, bioMerieux 2017/04

XII. ATTACHMENTS

Carba NP QC Form

G:\Micro\QC\Reagent QC Forms\Carba NP QC Form

Policy Title	Throat Culture	Policy #	LAB131058
Responsible	Laboratory Director	Revised/Reviewed	12/2020 10/18/2022

I. PURPOSE/PRINCIPLE

Strep screen cultures will identify only beta hemolytic Streptococcus while full throat cultures will show the predominant organisms present as well as ruling out beta Strep.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

BAP
SSA
CHOC (optional)
Catalase
PathoDX Strep Typing Kit

IV. STORAGE

Specimens should be set up as soon as possible once received in the laboratory. Specimens may be stored at 2-8°C if there is a delay in set up.

V. SPECIMEN

Pharynx swab

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

1. Observe media for small translucent or transparent colonies that are beta hemolytic.
2. Perform catalase test on one or two colonies. Catalase positive colonies are not streptococci.
3. Perform gram stain on catalase negative colonies. Organisms other than gram positive cocci in pairs or chains are not streptococci
4. Perform strep typing on colonies that are beta hemolytic, catalase negative gram positive cocci in pairs and chains.
5. Do not perform antimicrobial susceptibility testing, since all beta hemolytic strep continues to exhibit penicillin susceptibility.

VIII. INTERPRETATION

1. Groups A, C and G beta hemolytic streptococcus are considered pathogenic and should be reported along with semi-quantitation.
2. Antimicrobial susceptibility should not be performed.

Policy Title	Throat Culture	Policy #	LAB131058
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IX. REPORTING RESULTS

1. For Strep cultures, report cultures negative for beta hemolytic strep as "No Beta Hemolytic Strep isolated."
2. Report cultures positive for beta hemolytic strep with the strep type "Beta Strep Group A."
3. For Throat cultures, report the predominant organisms (or flora) present as well as beta Strep, if any, including semi-quantitation.

X. LIMITATIONS

N/A

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

N/A

Policy Title	BioFire	Policy #	MIC 131.068
Responsible	Laboratory Director	Revised/Reviewed	<u>09/2020</u> <u>10/18/2022</u>

I. PURPOSE/PRINCIPLE

The BioFire Respiratory Panel 2.1 (RP2.1) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), in nasopharyngeal swabs (NP) obtained from individuals suspected of COVID-19 by their healthcare provider. The following organism types and subtypes are identified using the BioFire RP2.1.

Viruses	Bacteria
Adenovirus	<i>Bordetella parapertussis</i>
Coronavirus 229E	<i>Bordetella pertussis</i>
Coronavirus HKU1	<i>Chlamydia pneumoniae</i>
Coronavirus NL63	<i>Mycoplasma pneumoniae</i>
Coronavirus OC43	
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	
Human Metapneumovirus	
Influenza A, including oseltamivir	
Influenza A, including oseltamivir	
Influenza A, including oseltamivir	
Influenza B	
Parainfluenza Virus 1	
Parainfluenza Virus 2	
Parainfluenza Virus 3	
Parainfluenza Virus 4	
Respiratory Syncytial Virus	

II. POLICY

The BioFire RP2.1 is a real-time, nested multiplexed polymerase chain reaction test designed to simultaneously identify nucleic acids from 22 different viruses and bacteria associated with respiratory tract infection, including SARS-CoV-2, from a single NP specimen. Specifically, the SARS-CoV-2 primers contained in the BioFire RP2.1 are designed to detect RNA from the SARS-CoV-2 in nasopharyngeal swabs in transport media from patients who are suspected of COVID-19. Internal controls are used to monitor all stages of the test process.

SARS-CoV-2 RNA and nucleic acids from the other respiratory viral and bacterial organisms identified by this test are generally detectable in NP swabs during the acute phase of infection. The

Policy Title	BioFire	Policy #	MIC 131.068
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detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results are indicative of the presence of the identified organism, but do not rule out co-infection with other pathogens. The agent(s) detected by the BioFire RP2.1 may not be the definite cause of disease.

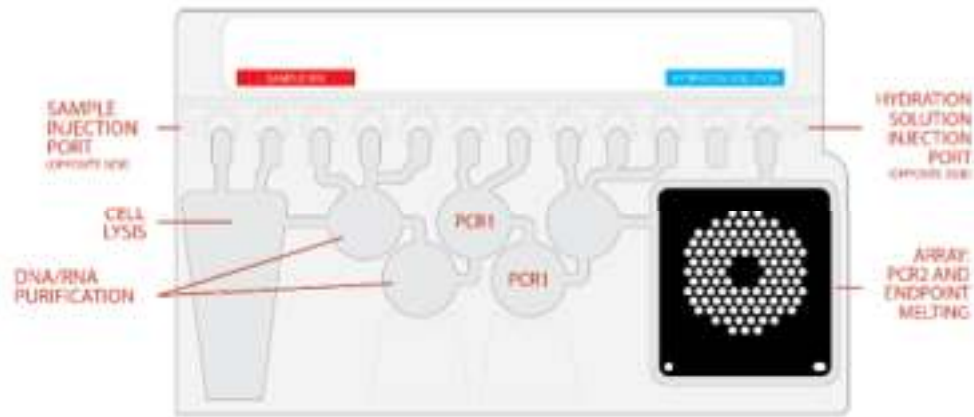
Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test, or lower respiratory tract infection that may not be detected by a NP specimen. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative SARS-CoV-2 results must be combined with clinical observations, patient history, and epidemiological information. Negative results for other organisms identified by the test may require additional laboratory testing (eg. bacterial and viral culture, immunofluorescence and radiography) when evaluating a patient with possible respiratory tract infection.

The RP2.1 pouch is a closed system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple respiratory pathogens within a single NP specimen. After sample collection, the user injects hydration solution and sample combined with Sample Buffer into the pouch, places the pouch into a BioFire FilmArray System instrument module, and starts a run. The entire run process takes about 45 minutes. Additional detail can be found in the appropriate BioFire FilmArray System Operator's Manual.

During a run, the FilmArray System:

- Lyses the sample by agitation (bead beating) in addition to chemical lysis mediated by the Sample Buffer.
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
 - First performing reverse transcription, followed by a multiplexed first stage PCR reaction (PCR1).
 - Then performing multiple simultaneous second-stage PCR reactions (PCR2) in the array to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect target-specific amplicons and analyses the data to generate a result for each analyte on the RP2.1.

Policy Title	BioFire	Policy #	MIC 131.068
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Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Materials provided:

Each BioFire COVID-19 Test Kit contains sufficient reagents to test 30 samples (30-test kit; 423744):

- Individually packaged BioFire RP2.1 pouches
- Single-use (1.0 mL) Sample Buffer tubes
- Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)
- Single-use Sample Injection Vials (red)
- Individually packaged Transfer Pipettes
- Instructions and Documents
 - BioFire COVID-19 Test - Quick Guide

Each BioFire COVID-19 Test External Control Kit (+) contains sufficient reagents for six positive control runs (6-control kit; 423748). Negative controls may be run using only the BioFire COVID-19 Test with no additional materials as described in the Quality Control section

- Individually -packaged BioFire COVID-19 External Control (+) Vials
- Instructions and Documents
 - BioFire COVID019 Test External Control Kit - Quick Guide

Policy Title	BioFire	Policy #	MIC 131.068
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Materials required but not provided:

- BioFire Pouch Loading Station
- 10% bleach solution or similar disinfectant
- Transport media
- BioFire COVID-19 Additional Documentation
 - BioFire COVID-19 Test - Patient Fact Sheet
 - BioFire COVID-19 Test - Provider Fact Sheet

IV. STORAGE

- **Specimens** should be tested immediately. If there is a delay in running a specimen, the sample may be held at room temperature (15-25°C) for up to 4 hours, refrigerated (2-8°C), or frozen ($\leq -15^{\circ}\text{C}$ or $\leq -70^{\circ}\text{C}$) for up to 30 days.
- Store the test kit, including reagent pouches and buffers, at room temperature (15 - 25°C). DO NOT REFRIGERATE.
- All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
- Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
- Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

V. SPECIMEN

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results

Policy Title	BioFire	Policy #	MIC 131.068
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Specimen Type	Nasopharyngeal Swab (NPS) collected according to standard technique and immediately placed in up to 3 mL of transport media
Minimum Sample Volume	0.3 mL (300 µL)
Transport and Storage	<p>Specimens should be processed and tested with the BioFire RP2.1 as soon as possible.</p> <p>If storage is required, specimens can be held:</p> <ul style="list-style-type: none"> • At room temperature for up to 4 hours (15-25 °C) • Refrigerated for up to 3 days (2-8 °C) • Frozen (≤-15 °C or ≤-70°C) (for up to 30 days)*

NOTE: Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.

VI. QUALITY CONTROL

BioFire Defense provides an external positive assayed quality control kit to monitor the performance of the BioFire COVID-19 Test performed the FilmArray Torch system. Good laboratory practice recommends running positive and negative external controls regularly. Evaluation of external controls is recommended prior to using a new shipment or new lot of BioFire COVID-19 Test Kits. Evaluation of external controls is also recommended when there is a new operator, and following replacement/repair of a FilmArray Torch system.

Controls are to be run each day of testing until we implement an IQCP; then controls will be run as directed by the IQCP.

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

Process Controls

Two process controls are included in each pouch:

1. RNA Process Control

The RNA Process Control assay targets a RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the BioFire COVID-19 Test were successful.

2. PCR2 Control

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that PCR2 was successful.

Policy Title	BioFire	Policy #	MIC 131.068
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Both control assays must be positive for the test run to pass. If controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The FilmArray software will automatically fail the run if the melting temperature TM for either the RNA Process Control or the PCR2 Control is outside of an acceptable range (80.3 - 84.4°C for RNA Process Control and 73.8 - 78.2°C for the PCR2 Control).

External Controls

For quality control and laboratory test verification, BioFire Defense provides an optional external positive assayed control kit to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of the BioFire COVID-19 Test performed on FilmArray Torch system. The BioFire COVID-19 Test External Control (+) kit is a surrogate control material comprised of dried synthetic RNA in buffer and stabilizer, supplied in an External Control Vial that is used directly with the BioFire COVID-19 Test. The RNA in the external control includes RNA segments to monitor whether the PCR primers for each SARS-CoV-2 assay are present for both stages of the nested PCR.

The BioFire COVID-19 Test External Control (+) Kit contains no biological hazards and is 100% non-infectious. This control is stored at 15-30°C. To run a positive external control, reference BioFire COVID-19 Test External Control Procedure (+) below or BioFire COVID-19 External Control Kit (+) Quick Guide. To run a negative external control, use the BioFire COVID-19 Test and reference BioFire COVID-19 External Control Procedure (-) below.

External Control Procedure (+)

- Follow Step 1 and Step 2 from the Test Procedure (See below) to prepare and hydrate the pouch.
- Use the Transfer Pipette provided in the test kit to draw the transport media or saline to the third line (approximately 0.3mL) of the Transfer Pipette. Add to the **Sample Injection Vial**.
- Using clean gloves, obtain a Sample Buffer Tube from the kit.
- Uncap the **External Control Vial (+)** and place the cap on a clean surface (a paper towel may be used).
- Add Sample Buffer to the **External Control Vial (+)**.
 - Hold the Sample Buffer Tube tip facing up and firmly pinch at textured plastic tab on the side of the tube until the seal snaps.
 - Invert the Sample Buffer Tube over the uncapped **External Control Vial (+)** and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.

Note: Avoid generating excessive foam.

- Recap the **External Control Vial (+)** and mix by gently inverting three (3) times.

Policy Title	BioFire	Policy #	MIC 131.068
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- Pour the rehydrated **External Control (+)** into the **Sample Injection Vial** and immediately dispose of the **External Control Vial (+)** and change gloves.
- Tightly close lid of **Sample Injection Vial** and mix by gently inverting at least three (3) times.
- Return **Sample Injection Vial** to **red well** of Pouch Loading Station.
- Continue at Step 4 of the Test Procedure (below) to load the pouch and run it on the FilmArray.

External Control Procedure (-)

- Follow Step 1 and Step 2 from the Test Procedure (See below) to prepare and hydrate the pouch.
- Use the Transfer Pipette provided in the test kit to draw the transport media or saline to the third line (approximately 0.3mL) of the Transfer Pipette. Add to the **Sample Injection Vial**.
- Using clean gloves, obtain a Sample Buffer Tube from the kit.
- Add Sample Buffer to the **Sample Injection Vial**.
 - Hold the Sample Buffer Tube tip facing up and firmly pinch at textured plastic tab on the side of the tube until the seal snaps.
 - Invert the Sample Buffer Tube over the **Sample Injection Vial** and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.

Note: Avoid generating excessive foam.

- Tightly close lid of **Sample Injection Vial**.
- Remove the **Sample Injection Vial** from the FilmArray Pouch Loading Station and invert the vial at least three (3) times.
- Return **Sample Injection Vial** to **red well** of Pouch Loading Station.
- Continue at Step 4 of the Test Procedure (below) to load the pouch and run it on the FilmArray.

Analysis of BioFire COVID-19 Test External Control (+) Assays

The BioFire COVID-19 External Control (+) passes when all three SARS-CoV-2 assays are 'Detected'. Positivity is evaluated by opening the report and confirming that 'Detected' is indicated to the left of each of the three assay names listed in the Result Summary. If any of the three SARS-CoV-2 assays have 'Not Detected' result, the External Control (+) fails and should be repeated. If the failure persists, contact BioFire Defense Customer Support for further instruction. Refer to Table 5 for interpreting the report Result Summary.

Policy Title	BioFire	Policy #	MIC 131.068
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Laboratories may decide to perform negative control testing on the system. In this case, after testing negative material (e.g., transport media or saline), the user should open the report and confirm that 'Not Detected' is indicated to the left of all three assay names listed in the Result Summary. If any of the three SARS-CoV-2 assays have a 'Detected' result, the External Control (-) fails and should be repeated after a thorough cleaning of the area. If the error persists, contact BioFire Defense Customer Support for further instruction.

Table 5. BioFire COVID-19 Test External Control (+) Interpretation of Results

Result Interpretation	Result Analysis	Action
External Control (+) Passes	Result Summary	Report the results.
	✓ Detected SARS-CoV-2	
	✓ Detected SARS-CoV-2a	
	✓ Detected SARS-CoV-2d	
	✓ Detected SARS-CoV-2e	
BioFire COVID-19 External Test Control (+) Failed Result	Result Summary	Repeat External Control (+) Testing. If the error persists, contact BioFire Defense Customer Support for further instruction.
	✖ Equivocal SARS-CoV-2	
	✓ Detected SARS-CoV-2a	
	Not Detected SARS-CoV-2d	
	Not Detected SARS-CoV-2e	
	Result Summary	
	Not Detected SARS-CoV-2	
	Not Detected SARS-CoV-2a	
	Not Detected SARS-CoV-2d	
	Not Detected SARS-CoV-2e	
BioFire COVID-19 External Control (+) Invalid Result	Result Summary	Repeat External Control (+) Testing. If the error persists, contact BioFire Defense Customer Support for further instruction.
	⚠ Invalid SARS-CoV-2	
	⚠ Invalid SARS-CoV-2a	
	⚠ Invalid SARS-CoV-2d	
	⚠ Invalid SARS-CoV-2e	

VII. PROCEDURE

Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and samples. Only prepare one BioFire COVID-19 Test pouch at a time and change gloves between samples and pouches. Once sample is added to the pouch, promptly transfer to the instrument to start the run. After the run is complete, discard the pouch in a biohazard container.

Refer to the BioFire COVID-19 Test Quick Guide or the appropriate FilmArray operator's manual for more details.

Step 1: Prepare Pouch

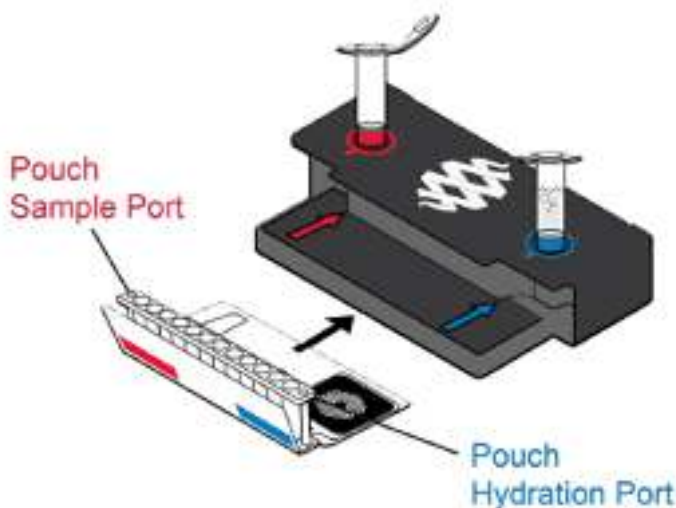
- Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.

Policy Title	BioFire	Policy #	MIC 131.068
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- Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

NOTE: The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

- Check the expiration date on the pouch. Do not use expired products.
- Insert the pouch into the FilmArray Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the FilmArray Pouch Loading Station.
- Place a **Sample Injection Vial** (with red cover) into the **red well** of the FilmArray Pouch Loading Station.
- Place a **Hydration Injection Vial** (with blue cover) into the **blue well** of the FilmArray Pouch Loading Station.



Step 2: Hydrate Pouch

- Unscrew the **Hydration Injection Vial** from the blue cover.
- Remove the **Hydration Injection Vial**, leaving the blue cover in the FilmArray Pouch Loading Station.
- Insert the **Hydration Injection Vial** cannula tip into the **pouch hydration port** located directly below the blue arrow of the FilmArray Pouch Loading Station.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------



- Forcefully push down in a firm and quick motion to puncture seal until a faint “pop” is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
 - If the hydration solution is not automatically drawn into the pouch, repeat Step 2 to verify that the seal of the **pouch hydration port** was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
- Verify that the pouch has been hydrated.
 - Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
 - If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the **pouch hydration port** was broken. If hydration solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

Step 3: Prepare Sample Mix

- Thoroughly mix the NPS sample by vortex or inversion.
- Use the Transfer Pipette provided in the test kit to draw the sample to the third line (approximately 0.3 mL) of the Transfer Pipette.
- Add the sample to the **Sample Injection Vial**.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------



- Discard the Transfer Pipette in a biohazard waste container.

NOTE: DO NOT use the Transfer Pipette to mix the sample once it is loaded into the Sample Injection Vial.

- Add Sample Buffer to the **Sample Injection Vial**.

- Hold the Sample Buffer Tube with the tip facing up.

NOTE: Avoid touching the tube tip during handling, as this may introduce contamination.

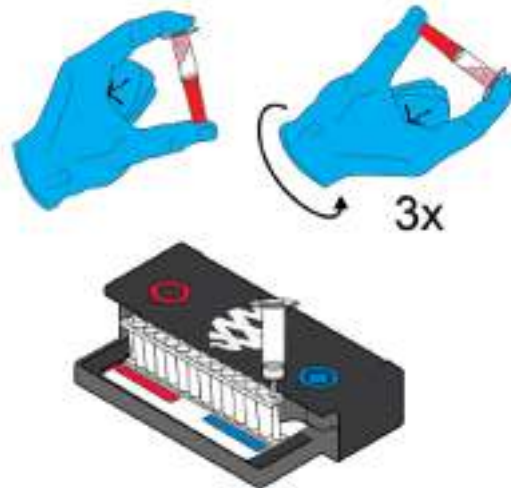
- Firmly pinch at textured plastic tab on the side of the tube until the seal snaps.
- Invert the tube over the red-capped **Sample Injection Vial** and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.

NOTE: Avoid squeezing the tube additional times. This will generate foam, which should be avoided.

WARNING: The Sample Buffer is harmful if swallowed and can cause serious eye damage and skin irritation.

- Tightly close the lid of the **Sample Injection Vial**.
- Remove the **Sample Injection Vial** from the FilmArray Pouch Loading Station and invert the vial at least 3 times to mix.

Policy Title	BioFire	Policy #	MIC 131.068
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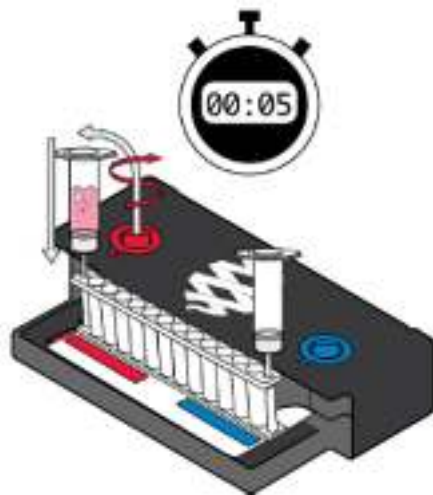


- Return the **Sample Injection Vial** to the red well of the FilmArray Pouch Loading Station.

Step 4: Load Sample Mix

- Slowly twist to unscrew the Sample Injection Vial from the red cover and wait for 5 seconds with the vial resting in the cover.

NOTE: Waiting 5 seconds decreases the risk of dripping and contamination from the sample.



- Lift the **Sample Injection Vial**, leaving the red cover in the well of the FilmArray Pouch Loading Station, and insert the **Sample Injection Vial** cannula tip into the **pouch sample port** located directly below the red arrow of the FilmArray Pouch Loading Station.
- Forcefully push down in a firm and quick motion to puncture seal (a faint “pop” is heard) and sample is pulled into the pouch by vacuum.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

- Verify that the sample has been loaded.
 - Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
 - If the pouch fails to pull sample from the **Sample Injection Vial**, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.
- Discard the **Sample Injection Vial** and the **Hydration Injection Vial** in a biohazard sharps container.
- Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample) and remove the pouch from the FilmArray Loading Station.

Note: Prior to removal from biosafety cabinet, run a bleach wipe or other disinfectant across the top of the pouch from the hydration port to the sample port and follow with a water wipe. This reduced the potential for contact with small amounts of sample mixed with sample buffer that may be retained at the sample injection port.

Step 5: Run Pouch

The FilmArray Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions are provided below. Refer to the appropriate FilmArray operator's manual for more detailed instructions.

- Ensure that the FilmArray Torch system is powered on.
- Select an available Module (instrument) on the touch screen or scan the barcode on the FilmArray pouch using the barcode scanner.
- Pouch identification (Lot Number and Serial Number), Pouch Type, and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire COVID-19 Test pouch.

- Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
- Insert the pouch into the available Module (instrument). Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module (instrument) will grab onto the pouch and pull it into the chamber.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

- If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire COVID-19 Test has a single NPS2 protocol available from the drop down list.
- Enter operator user name and password, then select Next.

NOTE: The font color of the user name is red until the user name is recognized by the software.

- Review the entered run information on the screen. If correct, select Start Run.
- Once the run has started, the screen displays a list of the steps being performed by the Module (instrument) and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.

- At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.
- The run file is automatically saved in the FilmArray database, and the test report can be viewed, printed, and/or saved as a PDF file.

VIII. INTERPRETATION

The BioFire COVID-19 Test contains three different assays (SARS-CoV-2a, SARS-CoV-2d, SARS-CoV-2e) for the detection of SARS-CoV-2. The FilmArray Software interprets each of these assays independently (as described above) and the results are combined as a final test result for the virus. For interpretation results, refer to Table 2.

Table 2. Interpretation Rules for the BioFire COVID-19 Test

SARS-CoV-2 Interpretation	Assay Results	Action
Detected	3/3 Assays 'Detected' 2/3 Assays 'Detected'	Report the Results
Equivocal	1/3 Assays 'Detected'	Retest the original sample and report the results of the retest. If the result of the retest is 'Equivocal' or 'Detected', the overall interpretation will be 'Detected'. If the retest is 'Not Detected', seek confirmatory testing.
Not Detected	0/3 Assays 'Not Detected'	Report the Results
Invalid	Invalid	Retest the original sample. If repeated errors occur, contact the BioFire Defense Customer Support Team. Refer to Table 3 for more information.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

If two or more assays are 'Detected', the result on the test report will be SARS-CoV-2 'Detected'. If all assays are 'Not Detected', the result on the test report will be SARS-CoV-2 'Not Detected'. If only one of the assays is 'Detected', the test report result will be SARS-CoV-2 'Equivocal'. If an 'Equivocal' result is obtained, retest the original sample using a new pouch. If the result of the retest is 'Equivocal' or 'Detected', the overall interpretation will be 'Detected'. If the retest is 'Not Detected', seek confirmatory testing. In cases where either or both of the control assays have failed, all results are reported as 'Invalid' and retesting is required.

The BioFire COVID-19 Test consists of three independent and non-overlapping assays targeting two SARS-CoV-2 open reading frame sequences: ORF1ab and ORF8. The target of each assay is shown in Table 1 below. The assays are designed to detect SARS-CoV-2 specifically. Detection of SARS-CoV-2 is based on the combined results of the three assays as described below.

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray operator's manual). The FilmArray Software then performs several analyses and assigns a final assay result for every well. The steps in the analyses are described below.

Analysis of Melt Curves

The FilmArray Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (T_m) of the curve and compares it against the expected T_m range for the assay. If the software determines that the T_m of the curve is within the assay specification T_m range, the melt curve is called positive. If the software determines that the T_m of the curve is not in the appropriate T_m range, the melt curve is called negative.

Analysis of Replicates

Once positive melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the T_m for at least two of the three positive melt curves must be similar (within 1.0°C). Assays that do not meet these criteria are called negative.

Table 1. Gene targets for assays on the BioFire COVID-19 Test.



Assay Name	SARS-COV-2 Genomic Region
SARS-CoV-2a	ORF1ab
SARS-CoV-2d	ORF1ab
SARS-CoV-2e	ORF8

IX. REPORTING RESULTS

Laboratories within the US are required to report all SARS-CoV-2 positive results to the appropriate public health authorities, namely, to the county health department in which the patient resides.

Policy Title	BioFire	Policy #	MIC 131.068
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The BioFire COVID-19 test report is automatically displayed upon completion of a run and can be printed or saved as a PDF file. Each report contains a Run Summary, a Result Summary, and a Run Details section.

 BioFire® COVID-19 Test v1.0		 www.BioFireDefense.com	
Run Summary			
Sample ID:	Example Report	Run Date:	31 Dec 2019 8:00 AM
Detected:	SARS-CoV-2	Internal Controls:	Passed
Equivocal:	None		
Result Summary			
		Viruses	
✓ Detected	SARS-CoV-2		
✓ Detected	SARS-CoV-2a		
✓ Detected	SARS-CoV-2b		
✓ Detected	SARS-CoV-2c		
Run Details			
Pouch:	COVID-19 Test v1.0	Protocol:	NPS2 v3.2
Run Status:	Completed	Operator:	Anonymous
Serial No.:	01234567	Instrument:	FA0000
Lot No.:	012345		

Run Summary

The **Run Summary** section of the test report provides the Sample ID, time and date of the run, internal control results, and an overall summary of the test results. If the SARS-CoV-2 interpretation is 'Detected', it will be listed in the 'Detected' field. If all of the assays are 'Not Detected' then 'None' will be displayed in the Detected field. Internal controls are listed as 'Passed', 'Failed', or 'Invalid'. Table 3 provides additional information for each of the possible internal control field results.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

Table 3. Interpretation of Internal Controls Field on the BioFire COVID-19 Test Report

Internal Controls Result	Explanation	Action
Passed	The run was successfully completed AND Both pouch controls were successful.	None Report the results provided on the test report
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch. If the error persists, contact BioFire Defense Customer Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error.)	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate FilmArray operator's manual or contact BioFire Defense Customer Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument.

Result Summary

The Result Summary section of the test report lists the result for the overall target and each individualized assay result. Possible results for each assay are 'Detected', 'Equivocal', 'Not Detected', or 'Invalid'. **Table 4** provides an explanation for each interpretation and any follow-up necessary to obtain a final result. According to the result for the target, 'Detected', 'Not Detected', 'Equivocal', or 'Invalid' will be indicated to the left of the target name.

If result is 'Equivocal', retest the original specimen using a new pouch and report the results of the retest. If the retest result is again 'Equivocal', the final result should be considered 'Detected'.

If result is 'Invalid', the controls are invalid. Typically this indicates a software or hardware error. Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to Table 3 and the Operator's manual for further information. Once the error is resolved, repeat the test using the original specimen and a new pouch or repeat the test using another module.

Policy Title	BioFire	Policy #	MIC 131.068
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Table 4. Reporting of Results and Required Actions

Result	Explanation	Action
Detected ³	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism were POSITIVE (i.e., met the requirements for a positive result described in the Assay Interpretation section above)	Report results.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism were NEGATIVE (i.e., did not meet the requirements for a positive result described in the Assay Interpretation section above)	Report results.
Equivocal	The run was successfully completed AND The pouch controls were successful (Passed) AND The combination of positive and negative assay results for Influenza A were inconclusive (see Table 2)	Retest the original specimen using a new pouch and report the results of the retest.
Invalid	The pouch controls were not successful (Failed) OR The run was not successful (Run Status displayed as: Aborted, Incomplete, Instrument Error or Software Error)	See Table 3, Interpretation of Control Field on the FilmArray Test Report for instruction.

³ If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

Run Details

The Run Details section provide additional information about the run including: pouch information (type, lot number, and serial number), run status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

X. LABORATORY PRECAUTIONS

Preventing Organism Contamination

Due to the sensitive nature of the BioFire COVID-19 Test, it is important to guard against contamination of the sample and work area by carefully following the testing process outlined in this instruction document, including these guidelines:

- Do not handle samples or pouches in a biosafety cabinet which is used for SARS-CoV-2 culture or immunofluorescence testing.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

- Prior to processing samples, thoroughly clean both the work area and the FilmArray Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue buildup and potential damage to the sample or interference from disinfectants, wipe disinfected surfaces with water.
- Samples and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and sample.
- Use clean gloves to remove materials from bulk packaging bags and reseal bulk-packaging bag when not in use.

Preventing Amplicon Contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the BioFire COVID-19 Test pouch is a closed system, the risk of amplicon contamination is low if pouches remain intact after the test is completed. Adhere to the following guidelines, in addition to those above, to prevent amplicon contamination:

- Discard used pouches in a biohazard container immediately after the run has completed.
- Avoid excessive handling of pouches after test runs.
- Change gloves after handling a used pouch.
- Avoid exposing pouches or sample injection vials to sharp edges or anything that might cause a puncture.
- Change gloves after loading the External Control (+) material
- Clean thoroughly after loading the External Control (+) material to avoid contamination with the External Control (+).

If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and workspace must be decontaminated.

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

XI. LIMITATIONS

- BioFire COVID-19 Test performance has only been established on the FilmArray 2.0 and FilmArray Torch systems.
- The BioFire COVID-19 Test is a qualitative test and does not provide quantitative value for the virus in the sample.
- The BioFire COVID-19 Test has not been validated for testing of samples other than nasopharyngeal swab specimens in transport media.

Policy Title	BioFire	Policy #	MIC 131.068
---------------------	---------	-----------------	-------------

- A false negative BioFire COVID-19 Test result may occur when the concentration of virus in the sample is below the device limit of detection.
- The detection of viral nucleic acid is dependent upon proper sample collection, handling, transportation, storage and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- There is a risk of false positive and false negative results caused by improperly collected, transported, or handled samples. The RNA process control and the PCR2 control will not indicate whether or not nucleic acid has been lost due to inadequate collection, transport, or storage of samples.
- As with any molecular test, mutations within the target regions of SARS-CoV-2 could affect primer binding, resulting in failure to detect the presence of virus.
- All three assays show 80% or greater homology to Bat coronavirus RaTG13 (accession:MN996532). In addition, the SARS-CoV-2e assay shows greater than 80% homology to Pangolin coronavirus isolate MP789 (accession: MT084071). It is unlikely that these isolates would be found in our sample matrix of nasopharyngeal swabs; however, little is known about their potential to infect a human host, or their evolutionary relationship to SARS-CoV-2.
- For *in vitro* diagnostic (IVD) use under Emergency Use Authorization only.
- Positive results are indicative of the presence of SARS-CoV-2 RNA
- Laboratories within the US and its territories are required to report all positive results to the appropriate public health authorities - to the county health department in which the patient resides.
- BioFire COVID-19 Test pouches are only for use with FilmArray 2.0 and FilmArray Torch systems.
- BioFire COVID-19 External Control Kit (+) is only for use with FilmArray 2.0 and FilmArray Torch systems.
- Always check the expiration date on the pouch. Do not use a pouch after its expiration date.
- FilmArray pouches are stored under vacuum in individually-wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that a FilmArray instrument / module will be available and operational before unwrapping any pouches for loading.
- Bleach introduced in a sample may damage nucleic acids in the sample, which may lead to a false negative result.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.

Policy Title	BioFire	Policy #	MIC 131.068
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- Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable clean powder-free gloves. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.
- Handle all samples and waste materials as if they were capable of transmitting infectious agents.
- Dispose of materials used in this assay, including reagents, samples, and used buffer tubes in biohazard waste bins.
- Sample Buffer is assigned the following classifications (refer to the SDS for more info):
- Acute toxicity (Category 4)
- Serious eye damage (Category 1)
- Skin irritation (Category 2)
- Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants. NEVER ADD BLEACH TO SAMPLE BUFFER OR SAMPLE WASTE.
- Bleach, a recommended disinfectant, is corrosive and may cause severe irritation or damage to eyes and skin. Vapor or mist may irritate the respiratory tract. Bleach is harmful if swallowed or inhaled.
- Eye contact: Hold eye open and rinse with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention.
- Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
- Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, seek medical attention.
- Please refer to the SDS for more information.

XII. REFERENCES

- Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
- BioFire COVID-19 Test - Instructions for Use, DFA2-PRT-0080-02, April 2020, BioFire Defense, LLC
- BioFire Respiratory Panel 2.1 (RP2.1), BFR0000-8303-01 May 2020, BioFire Defense, LLC

Policy Title	Gram Stain	Policy #	MIC2144
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/18/2022

I. PURPOSE:

Gram stain is a staining procedure which aides both in the visualization and the differentiation of bacteria. The differentiation would help with bacteria identification in subsequence steps. Organisms with a thick peptidoglycan component in their cell walls tend to retain the Crystal Violet stain and are referred to as gram-positive. Organisms in which the peptidoglycan layer composes only a small portion of the cell wall tend to loose the Crystal Violet stain with decolorization. These organisms are referred to as gram-negative.

II. PRINCIPAL:

Crystal Violet is taken up equally well by both gram-positive and negative bacterial cell walls. A crystal violet iodine complex is formed within the cell of each type of bacteria upon addition of iodine. When a decolorizer is applied, lipids are extracted from the cell walls of gram-negative bacteria. Lipid extraction causes an increase in cell wall permeability and results in the loss of the dye complex. The effect of decolorizer on gram-positive bacteria is dehydration. This decreases the cell wall permeability and increases the retention of the crystal violet iodine complex. The result is gram-positive bacteria appearing violet due to retention of the crystal violet iodine complex, and gram-negative bacteria appearing pink red due to the staining from the Safranin counterstain.

III. POLICY:

Gram stains can be done directly on patient specimens to aid in the diagnosis of infections or from culture plates to help identify those organisms. This policy and procedure is for Clinical Laboratory Scientists and Laboratory Technicians in the Microbiology section.

IV. REAGENTS:

Gram Stain Kit Advanced (GK400A)

- Crystal Violet (C008A), bottle appear dark violet
- Gram Iodine (I008N), bottle appear dark amber to brown
- Acetone (D008), bottle appear colorless
- Safranin (S008) , bottle appear red

V. STORAGE:

Upon receipt store products at 15-30° C away from direct light. The product may be used and tested up to the expiration date on the product label.

VI. SPECIMEN:

Blood, body fluids, wounds, sputum, stools, CSF, and miscellaneous.

VII. QUALITY CONTROL:

QC is performed on new lots of each staining and decolorizing reagent and at least weekly by the day shift with known gram-positive and gram-negative organisms. Personnel reading gram stains on the

Policy Title	Gram Stain	Policy #	MIC2144
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evening or night shift that do not normally work in Microbiology must perform at least one (1) QC when doing the patient gram stains.

Remel QC-Slide™ Gram Stain Control is a specially designed, unstained, ready-to-use microscope slide containing dried suspensions of known bacteria. The slides are intended to be part of the quality control program to monitor microbiological stains and staining techniques used in the Gram stain procedure.

If Remel QC-Slide™ Gram Stain Control is not available for purchase; the lab would create in-house QC slides to maintain the quality control program. QC slides are made in the following manner:

1. Prepare a faintly turbid broth (McFarland 2.0) culture of *Escherichia coli* (ATCC 25922) and *Staphylococcus aureus* (ATCC 25923 or 29213).
2. Write on the white end of each slide the made date as the lot number (e.g. 6/1/2018 = Jun12018, 9/18/2018 = Sep182018) with an expiration date of 10 years from the made date.
3. Make 101 slides using two (2) drops per slide spread in the size of a dime.
4. Fix in methanol or heat-fixed and store at -20° C.
5. Gram stain one (1) slide to verify contents.

VIII. PROCEDURE:

1. Rinse the slide with isopropyl alcohol to help fix body fluids to the slide.
2. Flood the slide with the Crystal Violet reagent for one (1) minute.
3. Rinse slide with deionized or tap water.
4. Flood the slide with Gram Iodine reagent for one (1) minute.
5. Gently rinse slide with deionized or tap water and allow to drain.
6. Tilt the slide and flood with a few drops of Decolorizer until no violet color runs off. This will usually takes 10 seconds or less. Do not over decolorize.
7. Rinse slide gently with deionized or tap water to remove excess Decolorizer.
8. Flood the slide with Safranin for one (1) minute.
9. Gently rinse slide with deionized or tap water and blot off excess water.
10. Allow slide to drain and air dry.
11. Examine slide under oil immersion lens (1000X magnification)

IX. INTERPRETATION:

Gram Positive organisms typically stain a very deep purple color. Gram Negative organisms stain light red or pink.

X. LIMITATIONS:

1. The application of the acetone is the most critical step in the staining process. The slide should be decolorized next to a stream of running tap water and rinsed immediately after the crystal violet stops running off the slide. Prolonged use of the acetone will over decolorize the Gram Positive cell wall of some organisms. If a slide is made too thick, the decolorization should stop as soon as the thin areas are decolorized. (The thick areas should not be viewed microscopically)
2. Gram Positive organisms that are no longer in log phase or have been damaged by antibiotics may lose their staining characteristics. Some organisms have cell walls intermediate in the amount of peptidoglycan and stain "Gram Variable." Other organisms like Mycobacteria do not take either component of the Gram's stain and are difficult to visualize by this process.

Policy Title	Gram Stain	Policy #	MIC2144
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3. The Gram stain will not detect organisms which exist within host cells (e.g., *Chlamydia* spp.), organisms with no cell wall (e.g., *Mycoplasma* spp. and *Ureaplasma* spp.), and organisms too small to be seen with light microscopy (e.g., spirochetes). Mycobacteria usually will not stain, and *Legionella* spp. stain only when taken directly from culture. Gram-negative bacteria that stain poorly with safranin include *Compylobacter* spp., *Legionella* spp., *Bacteroides* spp., *Fusobacterium* spp., and *Brucella* spp.
4. Certain conditions are known to damage the cell wall, causing gram-positive bacteria to falsely appear gram-negative or gram-variable. These include antibiotic treatment, cultures more than 48 hours old, inflammatory responses in the host, autolytic enzymes (e.g. *S. pneumonia*). To minimize ambiguous results, specimens should be collected before the patient begins antibiotic therapy. Also, Gram stains should be performed on colonies taken from culture media that do not contain antibiotics, preferably on colonies that are 18-24 hours old.
5. Fixation with excessive heat alters cell morphology and makes organisms more susceptible to over-decolorization.
6. Low concentrations of crystal violet make gram-positive organisms more susceptible to over-decolorization.
7. Insufficient exposure to iodine and lack of available iodine can prevent crystal violet from bonding firmly with the cell wall, thus making gram-positive organisms more susceptible to over-decolorization.
8. Prolonged decolorization, especially with acetone, can cause gram-positive bacteria to appear gram-negative. Insufficient decolorization can make gram-negative organisms falsely appear gram-positive.
9. Insufficient counterstaining can fail to stain gram-negative bacteria and background material, whereas excessive counterstaining will leach the crystal violet-iodine complex from gram-positive bacteria and stain them safranin, thus making them falsely appear gram-negative.
10. Prolonged washing between any of the steps can cause over-decolorization.

XI. REPORTING RESULTS

1. If no organisms or cells are detected in a smear of a clinical specimen, report "No organisms seen" or "No cells seen," respectively.
2. Determine number of bacteria and morphology (Table 1)
3. Notify the ordering physicians of positive blood culture gram stain and any clinically significant findings. Follow the Critical Tests policy. Document notification, including physician name, read back of result, date and time of notification, and CLS/caller initial in HMS.

Table 1

Enumeration of bacteria under oil immersion objective	Description of the morphology of bacteria
(Rare): <1/OILF	Gram positive

Policy Title	Gram Stain	Policy #	MIC2144
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(Few): 1-5/OILF	Cocci in pairs (and chains)
(Moderate): 6-30/OILF	Cocci in clusters
(Many): >30/OILF	Large bacilli/rods
	Small bacilli/rods
	Branching bacilli/rods
	Coryneform bacilli/rods
	Gram negative
	Diplococci
	Bacilli/rods
	Bacilli/rods, filamentous or pleomorphic
	Gram variable: coccobacilli
	Budding yeast cells
	Pseudohyphae

XII. ATTACHMENT

Gram Stain QC Log

XIII. REFERENCES:

1. Manual of Clinical Microbiology, 8th, ed. ASM, Washington DC.
2. Remel QC-Slide™ Gram Stain Control package insert, IFU 40142, September 24, 2013.
3. Gram Stain Kits and Reagents package insert. Hardy Diagnostics.
4. Aerobic Bacteriology, Analytical Considerations, 3.2.1.3, ASM Procedure Manual.

Policy Title	Anaerobic Culture	Policy #	MIC131002
Responsible	Laboratory Director	Revised/Reviewed	01/2021 12/15/2022

I. POLICY

Anaerobic bacteria are a significant component of the normal microbiota of the human host. There are anaerobes present on most body surfaces and mucous membranes. Anaerobes can cause infections when they increase in number in areas where they are part of the normal microbiota or when they are introduced into a new site in the body or when non-normal microbiota anaerobic bacterium gains entrance into the host via penetrating wounds. Anaerobic bacteria can cause a wide variety of infections.

To optimally recover anaerobic bacteria, appropriate collection, transport, and processing procedures must be followed. This policy should be used as a guide to collection, transport, and processing of specimens to ensure optimal anaerobe recovery and identification.

II. REAGENTS

Brucella agar
PEA agar
BBE agar
CHOC agar

III. STORAGE

All reagents to be stored in accordance with their respective policies. Specimens should be processed as soon as received in the laboratory. Large volumes of purulent material and large pieces of tissue maintain the viability of anaerobes for many hours. Swabs (when necessary) and small volumes of aspirated material, biopsy samples, or curetting should be transported in an anaerobic transport device. Avoid extreme heat and cold. *If delays are unavoidable, hold the specimen at room temperature until processing.*

IV. SPECIMEN

The proper specimen for anaerobic culture should be free of normal microbial contamination. Such contamination must be avoided to ensure proper interpretation of results and to prevent the identification of organisms that are not clinically significant. An aspirated fluid or tissue is best. These specimens must be processed immediately or put in anaerobic transport media. Aerobic cultures should always be run in tandem.

Collection of an anaerobic culture with a swab is strongly discouraged, especially when there are other means to obtain the sample more effectively. The volume of specimen that can adequately be obtained on a swab is small, reducing the probability that anaerobic pathogens will be recovered. Many organisms have a tendency to adhere to the fibers of the swab, which can also greatly reduce the recovery of anaerobes. When swabs are used, the specimen may be much more superficial than what can be obtained with an aspirate, which, again, could decrease recovery of the pathogen while potentially increasing the recovery of bacteria of the normal microbiota.

Policy Title	Anaerobic Culture	Policy #	MIC131002
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Unacceptable Specimens: Exudates, swab from burns, wound and skin abscesses are generally unacceptable for anaerobic culture. Cyst and abscesses are contaminated with normal flora unless aspirated with needle and syringe after the surface if intact tissue is disinfected. Catheterized urine is contaminated with distal urethral anaerobes, therefore unacceptable for aerobic cultures.

V. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VI. PROCEDURE

Set up

1. Transfer the prepared specimen onto the appropriate aerobic and anaerobic media.
2. Make slide for gram stain.
3. Streak plates for isolation.
4. Incubate at 35°C in anaerobic atmospheric conditions by using an anaerobe gas generating pouch system with indicator.

Culture Examination

All anaerobic cultures should be read at least once a day. Negative cultures can be finalized after 5 days of incubation.

1. Examine initially at 24 hours to verify anaerobic conditions have been met (observe the condition of the anaerobic indicator). **Do not open the anaerobic bags at 24 hours.**
2. Examine plates daily for colony growth.
 - a. If no growth is observed, continue incubation.
 - b. If growth is observed, select a single, well-isolated colony of each morphological type and transfer to a brucella and CHOC plate. The CHOC plate is to be incubated at 35°C aerobically and the brucella plate is to be incubated at 35°C in an anaerobe gas generating pouch system with indicator.
 - i. Observe CHOC the following day for growth (aero-tolerance check).
 1. Growth on CHOC implies the organism is not an anaerobe. No further work up is required, continue to incubate the anaerobic plates until 5 days has passed.
 2. If there is not growth on the CHOC aero-tolerance check:
 - a. Perform gram stain and record results in LIS.
 - b. Run ANC ID to ID the organism from growth on the subbed Brucella plate. Enter the gram stain results into the Vitek software either by the PC or when setting up the ID.

VII. INTERPRETATION

The extent to which an isolate needs to be classified is dependent on the source of the infection, the number of other organism present and specific requests from the physician. Since most anaerobic infections are polymicrobial, sensitivity testing of all isolates is rarely cost effective. Most non life-threatening infections need only be reported as a listing of the predominant obligate anaerobe types found (anaerobic cocci, anaerobic gram negative rod, etc.). All significant anaerobes isolated from

Policy Title	Anaerobic Culture	Policy #	MIC131002
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blood, CSF and bone cultures should be identified and an isolate held in case the physician requests it be sent out for susceptibility testing.

VIII. REPORTING RESULTS

Preliminary reports:

Release preliminary report for inpatient specimens after 48 hours

1. If no growth observed; Example: "No anaerobes isolated to date, final report to follow." (NOANA)
2. If anaerobic growth, release preliminary report for inpatient specimens after gram stain result is determined; Example: "Light growth anaerobic gram negative rod, ID to follow."

Final reports:

1. Release final report for all patients with no growth after 5 days of incubation; Example: "No anaerobes isolated after 5 days of incubation."
2. Release final report for all patients with organism ID(s) once the organism(s) have all been identified; Example: "Light growth *Bacteroides fragilis* and *Propionibacterium acnes*."

IX. LIMITATIONS

- The clinical specimen must be obtained properly and transported to the laboratory in a suitable anaerobic transport container.
- The microbiologist must be able to determine whether the anaerobic environment is indeed anaerobic.
- The microbiologist must perform aero-tolerance testing on each isolate recovered from the primary media to ensure that the organism is an anaerobe.

X. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XI. STAKEHOLDERS

N/A

Policy Title	Anthrax	Policy #	MIC131003
Responsible	Laboratory Director	Revised/Reviewed	01/2021 12/15/2022

I. PURPOSE

Bacillus anthracis, the agent of anthrax, is a zoonotic disease that is transmissible to humans through consumption or handling of contaminated products. Human infections in the US are very rare due to the mass livestock vaccination program over the last several decades. The organism does not normally multiply in the environment and human to human spread has only very rarely been reported from cutaneous infections. Anthrax is classified as a Tier I, Category A agent because of its suitability for use as a bio-threat agent in an attack or commission of a bio-crime.

There are three main disease presentations based on the route of infection.

1. **Cutaneous Anthrax** is by far the most common and most easily treated form. Anthrax spores generally enter through cuts or abrasions in the skin. Sin infection begins as a raised itchy bump or papule that resembles an insect bite. Within 1 to 2 days, the bump develops into a fluid-filled vesicle, which ruptures to form a painless eschar with a characteristic black necrotic area in the center.

The area should be cleaned and a culture and gram stain should be performed on the fluid from a freshly opened vesicle. If no vesicles remain the eschar may be lifted and the leading edge is swabbed for culture and gram stain. Cutaneous Anthrax generally responds well to antibiotic treatment but is 20% fatal without appropriate antibiotics.

2. **Gastrointestinal Anthrax** occurs 1 to 7 days following consumption of contaminated undercooked meat from infected animals. Characterized by acute inflammation of the intestinal tract. Initial signs of nausea, loss of appetite, vomiting and fever are followed by abdominal pain, vomiting of blood and severe bloody diarrhea.

Any hemorrhagic fluid from the eyes, mouth or anus should be cultured and gram stained. If not treated, the mortality rate ranges from 25 to 60%. Pharyngeal lesions may also occur.

3. **Pulmonary Anthrax** results from the inhalation of *B. anthracis* spores and can occur following an intentional aerosol release. Aerosolization of anthrax spores is regarded as the most likely method to be used in a bioterrorism event. Incubation period ranges from 1 to 6 days, depending on the quantity of aerosolized spores.

Disease onset is gradual and nonspecific. Fever, malaise, and fatigue may be present initially and be accompanied by a nonproductive cough and chest discomfort. Initial symptoms are often followed by a short period of severe respiratory distress. Shock and death usually occur within 24 to 36 hours following the onset of respiratory distress, and in later stages if therapy is not initiated within 48 hours following the onset of symptoms, with mortality reaching 95 to 100%.

Policy Title	Anthrax	Policy #	MIC131003
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II. **POLICY**

Rapid diagnosis and reporting are extremely important both in the management of individual patients and in alerting public officials of possible acts of bioterrorism. Early appropriate antibiotic treatment of Anthrax is crucial to the outcome of the clinical course. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. **REAGENTS**

Media: BAP, CHOC, MAC

Reagents: Catalase, gram stain reagents, disinfectant

IV. **STORAGE**

Specimens should be transported at room temperature.

V. **SPECIMEN**

Acceptable specimens include cutaneous swabs, stool, tissue, blood cultures, and CSF

VI. **QUALITY CONTROL**

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. **PROCEDURE**

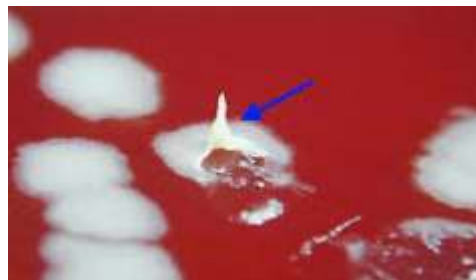
All cultures for Anthrax should be performed in the safety hood. All surfaces should be wiped with 1:10 bleach afterwards. All contaminated material should be sealed in double bags prior to autoclaving. *Bacillus anthracis* is a rapid growing aerobic gram positive rod that is easily cultured by standard methods. PEA agar should be added to the standard stool culture media if Anthrax is suspected to inhibit the competing enteric rods.

A suspicion of Anthrax must always be communicated to the microbiologist since nonpathogenic *Bacillus* species are not uncommon in clinical isolates. The presumptive identification of *Bacillus anthracis* can be determined by:

Colony Morphology:

Bacillus anthracis grows rapidly on standard media. After overnight incubation on a blood plate, colonies are 2 to 5 mm. in diameter. They are roughly round with an irregular border. Small coma shaped projections may be seen extending from the colonies; this is often referred to as "Medusa head" shape. The colonies often show spike or tailing projections follow the streak line. The colonies have a ground glass appearance similar to *B. cereus* but are not beta hemolytic. Colonies have a tenacious texture and can often hold a stiff peak if the edge of the colony is teased up with a loop.

Policy Title	Anthrax	Policy #	MIC131003
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<https://www.epa.gov/sites/production/files/2015-07/documents/cdc-anthrax.pdf>

https://www.labce.com/spg965586_bacillus_anthraxis.aspx

Gram Stain:

From direct clinical samples *B. anthracis* typically appears as a large regular gram positive rod (1 to 1.5 x 3 to 5 microns) in short chains. From culture, much longer chains may be seen. With age, the organisms tend to stain more irregularly. Long past log phase the organisms may stain as gram negatives. Spores are typically not seen in clinical samples due to high CO₂ concentrations. Spore formation can be encouraged on plated media by incubating in a nonCO₂ incubator. The length of time needed for spore formation in *Bacillus* species is quite variable. Repeated gram stains from both isolated colonies and from the main inoculum may be required. Spores of *B. anthracis* are large and oval and do not swell the rod.

Biochemical:

Catalase positive

Motility negative – do not use a wet mount to determine motility as it is potentially hazardous; use MIO media to determine motility.

VIII. INTERPRETATION

Presumptive ID of *B. anthracis*:

1. Large, gram positive rods, spores not normally observed.
2. Non-hemolytic, ground-glass colony morphology with a "Medusa head"
3. No growth on MAC
4. Catalase positive
5. Motility negative

IX. REPORTING RESULTS

Suspected cases of Anthrax must be reported immediately upon diagnosis. Non-motile spore-forming encapsulated gram positive rods with the gram stain and colony morphology as outlined above can be presumptively identified as *Bacillus anthracis*. The clinical symptoms should always be taken into consideration. Do not attempt full identification and susceptibility testing.

After consultation with the physician, if the clinical suspicion of Anthrax is high, the visualization of encapsulated gram positive rods may afford an early diagnosis. Consultation with the Microbiology Section Head and a Pathologist should be sought before reporting a case of Anthrax as long as this will not result in excessive delays. Cases of Anthrax are to be reported immediately to the attending physician as well all of the following:

Policy Title	Anthrax	Policy #	MIC131003
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Santa Clara County Public Health Lab 408-885-4272 or 24/7 call 408-885-4200 ask for Health Officer on call

California State PH Lab at Berkeley at 510-540-2408

All isolates of suspected Anthrax must be confirmed by the State Public Health Lab. For criminal cases the FBI may want to establish a chain of custody and personally deliver the specimen.

X. LIMITATIONS

- *Bacillus anthracis* is an infectious pathogen that requires the use of BSL 3 or BSL 2 with BSL 3 precautions for all manipulations of specimens and cultures.
- All patient specimens should be handled as BSL2 with BSL 3 precautions; wearing gloves and gown and working in a certified class II biosafety cabinet (BSC).
- Subcultures should be performed in a BSC and plates should be taped / shrink sealed and incubated in 5 to 10% CO₂. All additional testing should be performed only in the BSC while wearing gloves to prevent acquiring infection through the skin.
- Decontamination of the laboratory surfaces is easily accomplished using a fresh solution of 10% bleach. In addition, pipettes, needles, plastic loops, and microscopic slides should be soaked in 10% bleach or 10 to 30% formalin for 24 hours before being autoclaved.

XI. REFERENCES

A. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. STAKEHOLDERS

N/A

Policy Title	Bacterial Vaginosis Gram Stain	Policy #	MIC131004
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE/PRINCIPLE

Bacterial Vaginosis (BV) is a common condition caused by the shift of normal vaginal flora. BV is particularly important in pregnant women as it is a risk factor for obstetric sequelae such as low birth weight and premature delivery and is associated with miscarriage, amniotic infections and postpartum endometritis.

The microbiota of the vagina shifts from normally predominantly lactobacilli to a mixture of *Gardnerella vaginalis*, *Prevotella* spp., *Mobiluncus* spp and other anaerobes. *Gardnerella vaginalis* organisms appear as small gram variable pleomorphic bacilli, carrying from coccobacilli to longer rods, cells can palisade or appear coryneform and irregularly shaped. *Mobiluncus* spp. are curved gram negative rods. The comparison of relative numbers of lactobacilli (medium to large gram positive rods) with those of gram negative curved rods and gram variable coccobacilli allows for the diagnosis of BV to be made. Interpretation of these gram stains with Nugent's criteria remains the definitive laboratory method for diagnosis of BV.

II. POLICY

The BV gram stain is our preferred method for diagnosing Bacterial Vaginosis. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Crystal violet
Gram iodine
Gram decolorizer
Gram safranin
Glass slides

IV. STORAGE

All reagents to be stored at room temperature (see Gram Stain policy for further information).

V. SPECIMEN

Vaginal swab

VI. QUALITY CONTROL

See Gram Stain policy for quality control requirements.

VII. PROCEDURE

1. Stain Slide as outlined in the Gram Stain policy.
2. Report the gram stain results in the LIS.
3. Below the gram stain results add the "BV" canned comment.
4. Add the BV score to the canned comment

Policy Title	Bacterial Vaginosis Gram Stain	Policy #	MIC131004
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- The BV score is assigned by determining the average number of three bacterial morphologies per field. Scores for each morphotype are then added together for a total of 0 to 10 points.

VIII. INTERPRETATION

Use the table below to determine the score for each of the three organism types listed.

Organism	Number seen / HPF	Score
<i>Lactobacillus</i> (medium to large GPR)	>30	0
	5 – 30	1
	1 – 4	2
	<1	3
	0	4
<i>Mobiluncus</i> (curved GNR)	>5	2
	<1-4	1
	0	0
<i>Gardnerella</i> (tiny GVR or pleomorphic GVR)	>30	4
	5 – 30	3
	1 – 4	2
	<1	1
	0	0

Add the score for each to determine the total Nugent Score.

Total Score:

- 0-3 Morphotypes consistent with normal vaginal flora
- 4-6 Mixed morphotypes consistent with transition from normal vaginal microbiota
- 7-10 Mixed morphotypes consistent with bacterial vaginosis

IX. REPORTING RESULTS

- Report the gram stain results in the LIS. Be sure to include WBCs, RBCs, clue cells and yeast, if observed.
- Below the gram stain results add the “BV” canned comment.
- Add the BV score to the canned comment.

X. LIMITATIONS

Policy Title	Bacterial Vaginosis Gram Stain	Policy #	MIC131004
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- The application of the decolorizer is the most critical step in the staining process. The slide should be decolorized next to a stream of running tap water and rinsed immediately after the crystal violet stops running off the slide. Prolonged use of the reagent will over-decolorize the Gram Positive cell wall of some organisms.
- If a slide is made too thick, the decolorizer should be rinsed off as soon as the thin areas are decolorized. (The thick areas should not be viewed microscopically)
- Gram Positive organisms that are no longer in log phase or have been damaged by antibiotics may lose their staining characteristics. Some organisms have cell walls intermediate in the amount of peptidoglycan and stain "Gram Variable."
- Fixation with excessive heat alters cell morphology and makes organisms more susceptible to over-decolorization.
- Low concentrations of crystal violet make gram positive organisms more susceptible to over-decolorization.
- Insufficient exposure to iodine and lack available iodine can prevent crystal violet from bonding firmly with the cell wall, thus making gram positive organisms more susceptible to over-decolorization.
- Prolonged decolorization can cause gram positive bacteria to appear gram negative.
- Insufficient decolorization can make gram negative organisms falsely appear gram positive.
- Insufficient counterstaining can fail to stain gram negative bacteria and background material, whereas excessive counterstaining will leach the crystal violet / iodine complex from gram positive bacteria and stain them safranin, thus making them falsely appear gram negative.
- Prolonged washing between any of the steps can cause over-decolorization.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. STAKEHOLDERS

N/A

Policy Title	Body Fluid Culture (excluding CSF, Urine and Blood Cultures)	Policy #	MIC131011
Responsible	Laboratory Director	Revised/Reviewed	<u>01/2021</u> <u>12/15</u> <u>/2022</u>

I. PURPOSE/PRINCIPLE

Infection of normally sterile body fluids often results in severe morbidity and mortality; therefore, rapid and accurate microbiological assessment of these samples is important to successful patient management.

Any microorganism growing on an agar medium from a specimen collected from a normally sterile site must be considered significant, and all isolates reported. Sterile body fluids often submitted to the laboratory for culture include synovial, pleural, peritoneal and pericardial. Other sites may include fluid collected from drainage tubes such as, chest tube, G-tube, JP (Jackson-Pratt) tube, Duval catheter tip, etc.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

- BAP agar
- CHOC agar
- CNA agar
- MAC agar
- Thio broth
- Cytocentrifuge
- Glass slides
- Sterile pipettes

IV. STORAGE

Transportation of specimen to the laboratory is to be at room temperature. If there is an unforeseen delay in set-up, the specimen should be stored at 2-8°C until plate inoculation occurs. All body fluid specimens received (both processed and rejected) will be saved at 2-8°C for a minimum of 2 weeks.

V. SPECIMEN

Sterile Sites:

- Synovial
- Pleural
- Peritoneal
- Pericardial
- Amniotic
- Bile from Gallbladder
- Gastric

Policy Title	Body Fluid Culture (excluding CSF, Urine and Blood Cultures)	Policy #	MIC131011
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Body fluid samples submitted to the microbiology department must be collected aseptically and placed into appropriate sterile containers for transport to the laboratory. Acceptable sterile containers include, aerobic and anaerobic transport vials, blood culture bottles (aerobic and anaerobic), body fluid collection jars, syringe with needle removed and has been capped with a Luer-Lok, blood collection tubes without preservative, etc. See Anaerobic Culture Policy MIC.131.002 for details regarding specimens submitted for anaerobic culture.

Syringes must have the needle removed and must be capped with a Luer-Lok prior to transporting to the laboratory in order to prevent needle stick accidents and avoid leakage. Any specimen received with a needle attached may be rejected at the microbiologist's discretion.

All specimens must be labeled with patient demographics (including two forms of identification) and date, time, collection site (left knee joint fluid), and the name or initials of the person that collected the specimen. Specimens are to be delivered to the laboratory as soon as possible and transported at room temperature.

Rejection Criteria:

- Specimen received without two patient identifiers.
- Syringes received with needles attached.

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

A. Set up:

1. Inoculate BAP, CHOC, MAC and Thio broth with 2 – 3 drops of specimen. For specimens likely to contain a mixture of pathogens, such as peritoneal or abdominal fluid, add PEA or CNA plate and omit the Thio broth.
 - When requested, body fluids such as ascites fluid can be inoculated into blood culture bottles in addition to the concentrated plates to increase the sensitivity of the test.
2. Prepare smear for gram stain using cytocentrifugation. Microbiology staff will make two cytocentrifuge slides, one for the gram stain and one for Hematology then deliver slide to Hematology. If specimen is too thick for cytocentrifugation, place 1 or 2 drops of fluid on an alcohol-rinsed slide. Do not spread the fluid unless the smear is too thick for proper viewing. Allow slide to air dry in the biosafety hood or on the slide warmer in the hood. Stain slide according to the Gram Stain policy MIC.131.028.
3. Incubate plates at 35 to 37°C in 5% CO₂ or load blood culture bottles in BactAlert as per blood culture policy MIC.131.010, incubation time is 5 days.

B. Culture examination:

1. Examine all plated and broth media for macroscopic evidence of growth at 24 hours. If no growth is observed on the media, re-incubate and document observations in LIS. Read plates for 3 days. For specimens inoculated in blood culture bottles, incubate according to the blood culture policy (5 days), unless otherwise requested by physician.

Policy Title	Body Fluid Culture (excluding CSF, Urine and Blood Cultures)	Policy #	MIC131011
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2. Identify all organisms and test antimicrobial susceptibility using rapid tests and Vitek 2 (see Vitek Identification and Susceptibility Testing MIC.131.063).

VIII. INTERPRETATION

1. Generally, a positive culture indicates infection with the organism.
2. WBCs with predominating polymorphonuclear neutrophils are usually found with infections of body fluids.

IX. REPORTING RESULTS

1. Semi-quantitate growth (Rare or Scant, Light, Moderate or Heavy) along with the genus and species of each organism identified. An organism found in any sterile site is considered a critical value and must be handled appropriately.
2. Call and document any critical values as appropriate (see Critical Tests policy #2617).

X. LIMITATIONS

- False-positive cultures can result from contamination of the specimen with skin flora.
- False-negative results can be caused by low numbers of organisms, prior anti-microbial treatment, or the fastidious nature of the infective organism.
- Many organisms that are not easy to culture cause arthritis. These include *Borrelia burgdorferi*, the agent of Lyme disease.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

N/A

Policy Title	Botulism	Policy #	MIC131012
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE/PRINCIPLE

Botulism is a rare but serious illness caused by a toxin that attacks the body's nerves and causes difficulty breathing, muscle paralysis, and even death. This toxin is made by *Clostridium botulinum* and sometimes *Clostridium butyricum* and *Clostridium baratii* bacteria. The bacteria that make botulinum toxin are found naturally in many places, but it's rare for them to make people sick. These bacteria make spores, which act like protective coatings. Spores help the bacteria survive in the environment, even in extreme conditions. The spores usually do not cause people to become sick, even when they're eaten. But under certain conditions, these spores can grow and make one of the most lethal toxins known.

Botulism is caused by a potent neurotoxin produced from *Clostridium botulinum*, and rare strains of *C. butyricum* and *C. baratii*, which are anaerobic, spore-forming bacteria. Transmission differs by type of botulism:

- Foodborne botulism occurs when a person ingests botulinum toxin, which leads to illness within a few hours to days. Outbreaks of foodborne botulism have potential to be a public health emergency because the contaminated food may be eaten by other people. A frequent source is home-canned foods prepared in an unsafe manner.
- Infant botulism occurs each year in a small number of susceptible infants who harbor *C. botulinum* in their intestinal tract. It occurs when an infant ingests spores of *C. botulinum*, which in turn colonize the intestinal tract and produce toxin.
- Wound botulism is a rare disease that occurs when wounds infected with *C. botulinum* secrete the toxin. It occurs more frequently among persons who inject drugs, but has also been seen in cases of traumatic injury, such as motorcycle crashes, and surgeries.
- Adult intestinal colonization (also called adult intestinal toxemia) is an even rarer type of botulism. In the small number of these cases, most patients had a history of gastrointestinal surgery or illness, such as inflammatory bowel disease, which might have predisposed them to enteric colonization. Receiving antibiotics, which might alter the intestinal microbiome, or medications that alter the pH of the stomach may also be risk factors.
- Iatrogenic botulism occurs after an overdose of injected botulinum toxin for cosmetic or medical purposes

II. POLICY

In suspected cases of botulism, sentinel clinical laboratories will obtain appropriate specimens, ensure that they are packaged safely, and consult with the patient's physician, their designated Laboratory Response Network (LRN) reference laboratory and the CDC. Sentinel clinical laboratories are defined as those certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) by the Centers for Medicare and Medicaid Services for the applicable microbiology specialty. Laboratory in-house testing includes gram stains and at least one for the following: lower respiratory tract, wound or blood cultures.

Policy Title	Botulism	Policy #	MIC131012
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III. REAGENTS
N/A

IV. STORAGE
N/A

V. SPECIMEN

The suspicion of botulism is a public health emergency: notify both local public health officials and the state public health laboratory for approval to submit samples for testing. **DO NOT ATTEMPT TO CULTURE, IDENTIFY THE ORGANISM OR PERFORM TOXIN ANALYSIS.**

Handling of samples for identification

Due to the inherent dangers in working with *C. botulinum*, this laboratory is only responsible for the collection, packaging and shipment of specimens suspected of containing botulinum toxin. Submit all samples to Santa Cruz County Health Department

Botulism toxins are extremely poisonous. Exposure to the toxin represents the primary laboratory hazard. The 50% lethal dose of this toxin is 0.001 b/kg of body weight; therefore, acquisition by ingestion, inhalation or absorption can cause intoxication and death. All materials suspected of containing toxin must be handled using standard precautions and BSL 2 containment criteria.

Precautions

Additional primary containment and personnel precautions, such as those recommended for BSL 3, are indicated for activities with a high potential for aerosol or droplet production. A class II biological safety cabinet should be used when processing specimens to prevent the release of aerosols in the laboratory.

Decontamination procedures

C. botulinum is inactivated by a freshly prepared 1:10 dilution of household bleach. The disinfectant must be in contact with the toxin or organism for 15 to 20 minutes to ensure complete inactivation. If a spill is suspected of containing both the toxin and the organism, it should be treated sequentially with bleach and 1 M sodium hydroxide.

NOTE: Exposure to bleach does NOT inactivate spores of *C. botulinum*.

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

A. Infant Botulism(< 1 year old)

Stool specimens for diagnostic testing (serum not needed) from in-patients and outpatients with suspected infant botulism (California residents only) may be submitted to the Infant Botulism Treatment and Prevention Program (IBTPP) laboratory only after approval for such submission has been obtained from the IBTPP physician-on-call.

Specimens (if any) received without prior authorization will not be tested until such authorization is obtained. Physicians seeking such testing for their patient should contact the IBTPP at (510) 231-7600.

Policy Title	Botulism	Policy #	MIC131012
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B. Non-Infant Botulism (equal or greater than 1 year old)

Physicians or health providers requesting botulism testing should immediately contact their local Public Health Officer or designee to report the suspected botulism case and request testing.

Clinical laboratories that receive specimens for botulism testing should, immediately inform the physician to contact the local Public Health Officer or designee prior to sending the specimens. Once testing is approved, instructions will be provided to submit specimens for testing to the CDPH Microbial Diseases Laboratory (MDL). All specimens to MDL will be routed through the local public health laboratory.

The local Health Department will investigate to determine type of botulism (food, wound or unspecified). Diagnostic specimens (serum, stool, gastric) and/or food from possible adult botulism may be submitted to the local public health laboratory only after approval.

The local public health laboratory needs to review the MDL acceptance criteria (see MDLi82.i 03i07) before shipping. Specimens without the proper volume or conditions will not be tested. Email notification from the local public health laboratory, with an attached case history, is required to be sent to MDL prior to shipping. Specimens (if any) received without prior authorization will not be tested until such authorization is obtained.

VIII. INTERPRETATION

N/A

IX. REPORTING RESULTS

Immediately notify the LRN reference laboratory; it will provide this laboratory with guidance and recommendations for retaining the specimen or isolate.

Once the identification is confirmed, the laboratory is required to destroy the specimen or isolate (e.g., autoclaving). In particular, the appropriate material, including blood culture bottles, tubes and plates and actual clinical specimens (serum, feces, food, etc.) should be saved in a secure location until the reference laboratory confirms the identification.

Notify other public health authorities as required by California communicable disease reporting requirements if *C. botulinum* is suspected. The CA Public Health Department will notify other public ~~officials~~officials, as necessary. Full identification and susceptibility testing must not be performed at this laboratory.

Do not ship specimens the reference laboratory without prior arrangements.

The Infection Control department should be notified so further investigation of the patient's history can be made.

This laboratory must consult with the county laboratory prior to or concurrent with testing, if culture for *C. botulinum* is requested by the physician or a bioterrorist event is suspected. Obtaining guidance from the CDPH as appropriate (e.g., requests from local law enforcement or other local government officials).

If *C. botulinum* is ruled out, proceed with efforts to identify by using established procedures.

Policy Title	Botulism	Policy #	MIC131012
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If other cases are suspected or there is a laboratory exposure, collect samples to submit to the county for testing.

X. LIMITATIONS
N/A

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. Guidance for Laboratories on Reporting Select Agent Test Requests and Results. California Department of Public Health, January 2014

XII. ATTACHMENTS

Reference Services in Microbiology – Microbial Diseases Laboratory, State of California Department of Public Health Microbial Diseases Laboratory. MDL-N-158 April 2018
<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Reference-Services-in-Microbiology-MDL.pdf>

General Specimen Submission Instructions, Microbial Diseases Laboratory, State of California Department of Public Health Microbial Diseases Laboratory.
<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MDLGeneralSpecimenSubmissionInstructions.pdf>

Adult C. botulinum Toxin Detection Laboratory Request and Final Report Form, State of California Department of Public Health Microbial Diseases Laboratory. MDL-176/rev. Oct 2007
<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/MDL176.pdf>

Policy Title	Burkholderia	Policy #	MIC131014
Responsible	Laboratory Director	Revised/Reviewed	04/2024 12/15/2022

I. PURPOSE/PRINCIPLE

B. mallei and *B. pseudomallei* are infectious pathogens that can infect through the aerosol route. *Burkholderia mallei* is the etiologic agent of glanders, a febrile illness typically seen in equines. It is a non-motile, aerobic gram negative coccobacillus. *B. pseudomallei* was thought to cause a glanders-like illness in humans. This organism is an oxidase-positive, aerobic gram negative bacillus that is straight or slightly curved.

B. mallei and *B. pseudomallei* are considered Tear 1 select agents because they present the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure or public confidence. They are also considered "overlap select agents" because they not only have the potential to threaten public health but also animal health and products.

II. POLICY

This procedure describes the steps to recognize, rule out and presumptively identify these organisms in clinical specimens.

B. mallei infections can present either as cutaneous or systemic. The incubation period is typically 1 to 14 days. Patients with cutaneous infection will have nodules with accompanying localized lymphadenitis. The systemic illness usually manifests either as broncho- or lobar pneumonia. Bacteremia may also occur, resulting in lesions being seen in the liver and spleen. Infection in humans with *B. mallei* is often fatal without antimicrobial treatment.

Infections following laboratory exposure have been documented with both organisms from exposure to cultures of the *B. mallei* and *B. pseudomallei* in research settings. In reported cases, breaks in standard laboratory safety protocols were reported, emphasizing the importance of adhering to the standard BSL 2 safety practices with these organisms.

III. REAGENTS

N/A

IV. STORAGE

N/A

V. SPECIMEN

B. mallei and *B. pseudomallei* require the use of BSL 3 or BSL 2 with BSL 3 precautions of all manipulations of cultures. The initial culture of specimens can be performed with BSL 2 practices. All patient specimens and culture isolates should be handled while wearing gloves and PPE in a BSC. Subcultures should be performed in a class II BSC. Plates should be taped shut when incubating. All further testing should be performed only in the BSC while wearing gloves to protect from infections through the skin. Any procedure that may generate an aerosol, such as preparing suspension for identification systems (Vitek), must be performed in a BSL2 BSC with BSL 3 precautions. Avoid using

Policy Title	Burkholderia	Policy #	MIC131014
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a centrifuge and vortex. It is recommended that, if *B. mallei* and *B. pseudomallei* is suspected, that they be transferred to a BSL 3 facility as soon as possible.

Decontamination of laboratory surfaces is easily accomplished using a fresh solution of 10% bleach. Plates and specimens should be destroyed as directed by the LRN reference laboratory when identification is confirmed.

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

Presumptive ID of *Burkholderia* species:

B. mallei:

- Gram stain:
 - Small, straight or slightly curved gram negative coccobacillus with rounded ends. Cells are arranged in pairs, parallel bundles or Chinese-letter forms.
- Colony morphology:
 - Smooth, gray, translucent colonies in 2 days without pigment or distinctive odor.
 - Colonies may or may not grow on MAC. If they do grow on MAC, they may not look like typical gram negative rods, but will appear pinpoint colonies after 2 days.
- Biochemical tests:
 - Catalase positive
 - Oxidase variable (most are negative)
 - Indole negative
 - Non-motile
 - Does not grow at 42°C

Note: If the above reactions do not rule out *B. mallei*, do not use a commercial system (Vitek) to further identify *B. mallei*. Submit to LRN reference laboratory for confirmatory identification.

B. pseudomallei:

- Gram stain:
 - Gram negative rod that can demonstrate bipolar staining in direct specimens and peripheral staining in older cultures, which can mimic endospores.
- Colony morphology:
 - Creamy colonies which may change to dry, wrinkled colonies after a few days
 - Non-hemolytic
 - May grow on MAC
 - Often produces a distinctive musty or earthy odor, which is diagnostic
- Biochemical tests:
 - Oxidase positive
 - Indole negative
 - Motile
 - Grows at 42°C

Policy Title	Burkholderia	Policy #	MIC131014
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Note: Commercial gram negative identification panels (Vitek) CAN be used for preliminary identification of *B. pseudomallei* but the results should be evaluated in comparison with known limitations of the system.

- a) Identifications of *C. violaceum* for organisms that are not violet in color or are non-hemolytic could be *B. pseudomallei*
- b) Identifications of *B. cepacia* for organisms that are susceptible to amoxicillin-clavulanate could be *B. pseudomallei*
- c) Identifications of *B. cepacia* recovered from the blood or tissue of a non-cystic fibrosis patient could be *B. pseudomallei*
- d) Commercial systems that give "no identification" for an organism that screens as potentially *B. pseudomallei* could be *B. pseudomallei*

Note: If the above reactions do not rule out *B. pseudomallei*, submit to LRN reference laboratory for confirmatory identification.

Note: A gram negative rod that grows on BAP but not MAC should not be processed for ID by Vitek because of the danger of aerosol production.

VIII. INTERPRETATION N/A

IX. REPORTING RESULTS

If unable to rule out *B. mallei* or *B. pseudomallei*:

- a. Generate a report and notify the physician that *B. mallei* or *B. pseudomallei* species cannot be ruled out.
- b. Do not attempt full identification and susceptibility testing.
- c. Immediately notify the county health department. They will provide guidance and recommendations for retaining the specimen or isolate and submission for confirmative identification.
- d. Preserve original specimens pursuant to a potential criminal investigation and transfer to the county health department as instructed. In particular, the appropriate material, including blood culture bottles, tubes and plates, and actual clinical specimens (aspirates, biopsies, sputum, etc.) should be documented, and either submitted or saved until identification confirmation.
- e. Do not send to county health department without prior arrangements.
- f. Notify Infection Control or infectious disease if patient has been admitted

If *B. mallei* or *B. pseudomallei* are ruled out, proceed with efforts to identify by using established procedures.

Special considerations:

1. Antimicrobial susceptibility testing of *B. mallei* and *B. pseudomallei* is not appropriate for our laboratory to perform.
2. There are no case controlled trials for treatment of either *B. mallei* or *B. pseudomallei*. Therapeutic choices are based on case series and expert clinical experience. Additionally, there is a paucity of clinical experience for treating *B. mallei* infections with "modern" antimicrobials such as third-generation cephalosporins, carbapenems, β -lactamase inhibitors / β -lactams and fluoroquinolones, so antimicrobial recommendations for treatment of *B. mallei* are the same as those for *B. pseudomallei*. Current recommendations for treatment of *B. pseudomallei* are to initially administer ceftazidime,

Policy Title	Burkholderia	Policy #	MIC131014
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meropenem or imipenem for 10 to 14 days, followed by prolonged oral eradication therapy with trimethoprim / sulfamethoxazole for 3 to 6 months.

3. Post-exposure prophylaxis for laboratory workers is recommended following laboratory exposure for both *B. mallei* and *B. pseudomallei*. Trimethoprim / sulfamethoxazole is the drug of choice; for patients who cannot tolerate this agent, amoxicillin-clavulanic acid or doxycycline may be used as alternatives. Because of high failure rates in treatment of clinical cases of melioidosis, ciprofloxacin is not recommended.

When to refer to the LRN reference laboratory:

1. Naturally occurring cases of *B. mallei* are extremely rare in humans and should be referred to LRN reference laboratories in all cases.
2. Naturally occurring cases of *B. pseudomallei* may be observed in any of the following situations. Confirmation of the identification of these isolate may be requested from a LRN reference laboratory, but they are unlikely to represent a bioterrorism event. Patient who cannot be classified into any of the following patient populations may represent a bioterrorism event.
 - a. Patients with acute infection who have a recent history of travel to the region of endemicity. This includes Southeast Asia (in particular, Thailand, Vietnam, Myanmar, or Taiwan), the Philippines, the Indian subcontinent, or the northern coast of Australia. Recent US cases have also been imported from countries bordering the Caribbean. Cases have been reported in Brazil, so *B. pseudomallei* may also be considered, for bio-threat reasons, as endemic in tropical regions of Central and South America.
 - b. Recent immigrants or visitors from the region of endemicity.
 - c. Patients with recent onset of diabetes mellitus, renal failure, or immunosuppressed states who have traveled in the region of endemicity mentioned above even if that travel occurred decades before.
 - d. Individuals (such as zoo employees) who work with animals that have recently been imported from regions of endemicity.
 - e. Individuals who work in laboratories where they may be exposed to this organism.

Select agent reporting and compliance:

1. Reporting of all identified select agents is still required, even though sentinel clinical laboratories are not required to register under the Select Agent Rule.
2. The laboratory must complete form 2 within 1 week (7 days) following notification of the confirmed identification. For further guidance and access to the necessary forms, consult with the county health department or refer to the CDDC Division of Select Agents and Toxins website at www.selectagents.gov
3. Reporting all identified select agent is required by completing form 4A within 7 days of confirmed identification. If the isolate is from a proficiency test sample, form 4B is to be completed within 90 days of receipt of the sample.

X. LIMITATIONS

- Do not attempt to identify gram negative rods that do not grow on MAC using the Vitek because of their lack of accuracy and danger of aerosols.

Policy Title	Burkholderia	Policy #	MIC131014
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- Understand that *B. pseudomallei* infections may be naturally occurring and may not represent a biocrime. The infected patient's potential exposure to naturally occurring *B. pseudomallei* either due to travel or workplace exposures should be determined.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. Guidance for Laboratories on Reporting Select Agent Test Requests and Results. California Department of Public Health, January 2014

XII. ATTACHMENTS

Reference Services in Microbiology – Microbial Diseases Laboratory, State of California Department of Public Health Microbial Diseases Laboratory. MDL-N-158 April 2018

<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Reference-Services-in-Microbiology-MDL.pdf>

General Specimen Submission Instructions, Microbial Diseases Laboratory, State of California Department of Public Health Microbial Diseases Laboratory.

<https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MDLGeneralSpecimenSubmissionInstructions.pdf>

Policy Title	Catheter Tip	Policy #	MIC131016
Responsible	Laboratory Director	Revised/Reviewed	04/2024 12/15/2022

I. PURPOSE

Intravascular catheter insertions cause a break in the skin barrier amenable to infection. The continued presence of this foreign body predisposes further to infection, which can result from either colonization of the catheter by the cutaneous microbiota or, less commonly, hematogenous seeding due to hub contamination. Since infected catheters are usually exposed directly to sterile spaces, there is a risk that the infection will result in bacteremia.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

BAP agar
Various biochemicals

IV. STORAGE

Store at room temperature until samples can be transported or processed by the laboratory. Do not refrigerate.

V. SPECIMEN

Catheter tips in sterile cup

- Remove catheter and submit 1 to 3 inches of the distal end of the tip to the laboratory for culture.

Rejection criteria

- Urinary Foley catheter tips
- Chest tube tips
- Abdominal drainage tips
- Tips placed in saline or any other transport media

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

Set up:

1. Using sterile forceps, remove cath tip from transport container
2. Lay on BAP
3. Roll the tip back and forth across the entire plate
 - a. If the tip is too long, using sterile scissors or scalpel, cut the end closest to the top of the tube (proximal end) prior to rolling on the plate

Policy Title	Catheter Tip	Policy #	MIC131016
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4. Incubate at 35°C in CO₂ incubator.

Culture examination:

1. Examine all plates and broth media for evidence of growth at 24 hours. Incubate plates and read daily for 4 days.
2. Count each type of colony isolated
3. Identify at least to the genus level any of the following:
 - a. Each organism present from vascular cath tip with colony counts of > 15 CFU, including gram positive rods
 - b. Counts < 15 CFU, identify only significant pathogens (e.g., *C. albicans*, group A strep, gram negative rods).
4. Susceptibility testing should be performed on all significant isolates from vascular catheters or grafts and central nervous system shunts even when the same organism is identified in the patient's blood. Since catheter tip infections are due to the formation of a biofilm on the device, different morphotypes of the same organism (e.g., two or more species of coagulase negative *Staphylococcus*) may be recovered from the blood and the device. These morphotypes may have different antimicrobial susceptibility profiles, and therapy should be antimicrobial directed against the most resistant isolate.

VIII. INTERPRETATION

Antimicrobial susceptibility testing should be performed on isolates from both blood and from catheter tip and other segments submitted to the laboratory for culture. Different bacterial morphotypes isolated from the blood and the catheter may be recognized by variations in their antibiogram profiles. If a central catheter cannot be immediately removed for clinical reasons (e.g., risk of bleeding), then antimicrobial therapy is directed against the susceptibility profile of the blood culture isolate.

An isolate from a catheter tip that is the same as from a blood culture collected near the same time is indicative of catheter related blood stream infection.

The presence of > 15 CFU suggests the catheter as a potential source of bacteremia, which occurs with about 10% of colonized catheters.

IX. REPORTING RESULTS

Organisms are not enumerated in catheter tip cultures as few, moderate or many. Organisms are enumerated as colony forming units (CFU).

1. Report preliminary negative cultures as "No growth in x days, final report to follow" and final negative cultures as "No growth in 3 days."
2. For any morphotype with a count of > 15CFU
 - a. Enter the number of CFU isolated for each organism, e.g., 18 CFU, followed by the organism name at least to the genus level.
 - b. If > 15 CFU of different morphologies of coagulase negative staphylococci are present, report "x CFU of coagulase negative staphylococci (mixed morphologies)."
3. For any morphotypes < 15 CFU
 - a. Report significant pathogens by name
 - b. Group together mixed skin microbiota organisms (i.e., coagulase negative *Staphylococcus*, diphtheroids or viridans group strep) as "< 15 CFU mixed skin flora"

Policy Title	Catheter Tip	Policy #	MIC131016
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- c. Report minimal identification of pure cultures of skin microbiota, e.g., staphylococci or gram positive rods.
4. If organisms are too numerous to count, report as "> 100 CFU"

X. LIMITATIONS

- Semi-quantitative catheter tip cultures are estimated to have a sensitivity of 85% in diagnosis of catheter-related bacteremia, but the specificity to diagnose catheter-related sepsis is low. Blood cultures collected from peripheral sites are helpful in confirmation of the diagnosis of catheter-related sepsis.
- Infections of the catheter hub lumen may be missed by culture of only the tip.
- Efforts to diagnose catheter-related sepsis using unpaired quantitative blood cultures drawn from the catheter are less sensitive than tip cultures.
- Catheter cultures can be helpful in determination of the cause of fever.
- Some studies suggest that antimicrobial treatment of patients with positive catheter tip cultures but negative blood cultures increase medical costs unnecessarily, because of the low specificity of catheter tip cultures. For this reason, susceptibility testing of catheter tip isolates is not indicated. If concomitant blood cultures are positive, antimicrobial testing of the blood culture isolate is appropriate. Exceptions include performing antimicrobial testing when specifically requested by a physician and when testing the catheter tip isolate would provide more rapid results than waiting for the companion blood culture isolate to be tested.
- In simulated studies, rolling catheters, impregnated with antiseptics, on a blood plate inhibited the ability of the organisms to grow on the agar. This suggests that alternative methods must be found to diagnosis infections in antiseptic-impregnated catheters.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

ATTACHMENTS N/A

Policy Title	Beta-Lactamase (Cefinase)Test	Policy #	MIC131017
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/18/2022

I. PURPOSE/PURPOSE

Cefinase discs are intended for use in rapid testing of isolated colonies of *Haemophilus influenzae* for the production of beta-lactamase. The Cefinase disk is impregnated with the chromogenic cephalosporin, nitrocefin. The compound exhibits a very rapid color change from yellow to red as the amide bond in the β -lactam ring is hydrolyzed by a β -lactamase. When a bacterium produces this enzyme in significant quantities, the yellow-colored disc turns red in the area where the isolate is smeared.

Although other penicillins and cephalosporins may be used as substrates for specific enzymes, nitrocefin has the wide spectrum of susceptibility and sensitivity of the commercially available β -lactams. It is not known to react with other microbial enzymes.

II. POLICY

Testing to be performed by the Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Cefinase Discs

IV. STORAGE

Upon receipt, store unopened package at -20 to +8° C. After use, the Cefinase cartridge should be stored in any glass, air tight container containing desiccant and stored at -20 to +8° C. Discard remaining Cefinase discs 60 days after opening blister packaging. The expiration date on the cartridge applies only to discs intact in unopened blister packaging.

**Do not use if discs appear orange or red in color.

V. SPECIMEN

This procedure is to be used only for *Haemophilus influenzae* isolated from clinical specimens such as wound, sputum and body fluid.

VI. QUALITY CONTROL

Control reference organisms should be run with each group of patient specimens, new lot and/or new shipment as follows:

<i>Staphylococcus aureus</i> (ATCC 29213):	Positive control
<i>Haemophilus influenzae</i> (ATCC 12011):	Negative control

Control results to be recorded on the Cefinase Disc QC Log.

VII. PROCEDURE

- Using a single disc dispenser, dispense the required number of discs from the cartridge onto a microscope slide.

Policy Title	Beta-Lactamase (Cefinase)Test	Policy #	MIC131017
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2. Moisten each disc with one drop of deionized water.
3. With a sterilized loop or applicator stick remove several well-isolated similar colonies and smear onto a disc surface. (Alternate procedure: using forceps moisten disc with one drop of deionized water then wipe across colony.)
4. Observe disc for color change.

VIII. INTERPRETATION

A positive reaction will show a yellow to red color change on the area where the culture was applied. Note: color change does not usually develop over the entire disc.

A negative reaction will show no color change on the disc.

For most bacterial strains, a positive result will develop within 5 minutes. However, positive reactions for some staphylococci may take up to 1 hour to develop.

Organism	Result	Approximate Reaction Time	Interpretation
<i>Staphylococcus aureus</i>	Positive	1 hour	Resistant to penicillin, ampicillin, carbenicillin and ticarcillin. Probably susceptible to cephalothin, methicillin, oxacillin, nafcillin and other penicillinase-resistant penicillins.
<i>Haemophilus influenzae</i>	Positive	1 minute	Resistant to ampicillin. Susceptible to cephalosporins.

IX. REPORTING

Result will be entered under organism name in HMS

Beta-Lactamase Testing: Positive (Negative)

A positive beta-lactamase test result indicates resistance to ampicillin and susceptibility to cephalosporins. A negative result implies but does not guarantee susceptibility.

X. LIMITATIONS

The efficacy of this test in predicting the β -lactam resistance of microorganisms other than *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Moraxella catarrhalis*, staphylococci, enterococci and certain anaerobic bacteria is unproven. Resistance to β -lactam antibiotics has been on rare occasions reported in some of the above organisms without the production of β -lactamases. In these cases, resistance mechanisms such as permeability barriers have been postulated. Therefore, the β -lactamase test should be used as a rapid supplement and not a replacement for conventional susceptibility testing.

Policy Title	Beta-Lactamase (Cefinase)Test	Policy #	MIC131017
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XI. REFERENCES

1. BD BBL Paper Discs for the Detection of β -Lactamase Enzymes (Cefinase Discs), 2015-04
2. Clinical Microbiology Procedures Handbook 4th Edition (ASM Press) by Amy L.

XII. ATTACHMENTS

Cefinase Disc QC Log
(G:\Micro\QC\Reagent QC Forms\Cefinase Disc QC Form)

Policy Title	Ear Culture	Policy #	MIC131021
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

Otitis media is an infection of the middle ear and is one of the most common reasons children under 5 visit the pediatrician's office. Tympanocentesis and culture of the middle ear fluid are valuable tools for definitive diagnosis, guiding therapy and evaluating treatment failures. However, the diagnosis is usually made on clinical grounds because of the invasive nature of tympanocentesis. Culture is usually reserved for persistent infections.

Otitis externa is an infection of the external auditory canal. Unique problems occur with this infection because of the narrow and tortuous nature of the canal and its tendency to trap foreign objects, wax and water. Infections are classified as acute and chronic. Acute infections are often referred to as "swimmer's ear." *Pseudomonas aeruginosa* is a frequent cause of freshwater otitis, and *Vibrio alginolyticus* is a cause in oceanic swimmers, although other aerobic bacteria can be involved.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

BAP / CHOC / MAC agar plates
Glass slides
Gram stain reagent
Optochin discs
Various biochemicals and other rapid tests

IV. STORAGE

Store at room temperature until samples can be transported or processed by the laboratory. If specimen transport is delayed, store 2 - 8°C.

- A delay in processing of more than 2 hours may result in a decreased ability to recover fastidious pathogens, such as *S. pneumoniae* and *H. influenza*, and/or overgrowth of flora.

V. SPECIMEN

External ear swabs, tympanocentesis fluid in syringe (without needle) or sterile container.

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

Specimen Processing:

1. Process specimens as soon after receipt as possible in order to maintain the viability of the primary pathogens.

Policy Title	Ear Culture	Policy #	MIC131021
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2. After the plates are set up, a gram stain slide should be made with the same swab. The slide should air dry on the heat block then be promptly stained.
3. Incubate plates at 35 to 37°C in 5% CO₂ for 48 to 72 hours.

Determining pathogens:

1. Observe plates for growth daily for a total incubation time of 72 hours.
2. Identify the potential pathogens that grow in significant amounts and are not part of the normal skin flora (see Identification of pathogens section below for guidelines). Significant growth is defined as:
 - a. Moderate to heavy growth of an isolate in second or third quadrant of the plate.
 - b. Small amounts of a primary pathogen in the culture that is consistent with the predominant morphotype seen in the original gram stain.
3. Subculture to BAP, CHOC or MAC to obtain isolated colonies for accurate identification from mixed cultures.

Workup of Isolates:

1. Gram Negative Rods:
 - a. Perform spot indole and oxidase test. Record results in LIS
 - b. Perform GN ID and AST (GNS).
2. Staphylococci:
 - a. Perform catalase test. Record results in LIS
 1. Perform Staph latex,
 - a. If positive provide preliminary ID as *Staphylococcus aureus*. Perform AST (GPS). Perform PBP2 test if inpatient (see PBP2 policy).
 - b. If negative, report as normal skin flora
3. Streptococci and other catalase-negative cocci:
 - a. Alpha hemolytic:
 1. Heavily inoculate a BAP with well isolated alpha colony.
 2. Using sterile technique, place a P disc according to the Optochin procedure.
 3. Incubate at 35°C overnight in CO₂ incubator.
 - a. If no zone around P disc, report as normal respiratory flora.
 - b. If zone around P disc ≥ 14mm, provide preliminary ID as presumptive *Streptococcus pneumoniae*. Perform confirmatory GP ID and AST (STO2).
 - c. If zone around P disc is between 6 and 14mm, perform bile solubility (see Bile Solubility 2176) and confirmatory GP ID and AST (STO2).
 - b. Beta hemolytic:
 1. Perform catalase, should be negative, record results in LIS
 2. Perform Strep typing, record results in LIS
 3. Provide preliminary result with organism name or Lancefield group.
 4. Set up AST (STO2).
 - c. Enterococci (gamma hemolytic)
 1. Perform catalase, should be negative or weakly positive, record results in LIS
 2. Perform PYR, should be positive, record results in LIS
 3. Provide preliminary result as "Gamma Streptococcus, usually *Enterococcus* species, ID to follow."
 4. Set up GP ID and AST (GPS).

Policy Title	Ear Culture	Policy #	MIC131021
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4. Gram Positive Rods:
 - a. Examine for large, spore-forming gram positive rods, if present perform ANC ID to rule out *Bacillus anthracis* and *Bacillus cereus*.
 - b. Generally, do not pursue other gram positive rods, as they are unlikely to cause pneumonia.
5. Gram Negative Coccobacilli and Diplococci:
 - a. Perform oxidase test, record results in LIS
 - b. Set up NH ID.
 - c. If organism is *H. influenzae*, perform beta-lactamase test (see Cefinase Disc policy), record results in LIS and include in final report.
6. Yeast:
 - a. Review gram stain to confirm yeast seen, record results in LIS.
 - b. If insufficient growth on BAP, sub to SAB and incubate in fungus or CO₂ incubator.
 - c. If sufficient growth on BAP and yeast has "feet," report as presumptive *Candida albicans*. If no feet, report preliminary result as "Yeast species, ID to follow."
 - d. Set up Yeast ID.

Common Normal Flora:

Coagulase negative staphylococci

Viridans group streptococci

Corynebacterium

P. acnes

Common Pathogens:

Haemophilus influenzae

Streptococcus pneumoniae

Staphylococcus aureus

Beta Streptococcus

Gram negative rods

Neisseria gonorrhoeae

Moraxella spp.

VIII. INTERPRETATION

- A positive external ear culture with a predominant gram negative rod, beta hemolytic streptococci, or *S. aureus* generally indicates infection with that organism.
- A positive middle ear culture with *S. pneumoniae*, *H. influenzae*, *M. catarrhalis* and *A. otitidis* generally indicates infection with that organism.
- A negative culture cannot rule out otitis media. In fact, in chronic infections, a pathogen is often not isolated.
- Controversy regarding the need for treatment of otitis media has been found in recent literature, but most physicians agree on its benefits. *A. otitidis* is resistant to sulfamethoxazole-trimethoprim and often to erythromycin, but it does not have a beta-lactamase.

Policy Title	Ear Culture	Policy #	MIC131021
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- Otitis externa is usually treated with ear drops containing a variety of agents, including 2% acetic acid, hydrocortisone, and antimicrobial agents, such as quinolones, neomycin, and either gentamicin or polymyxin B.

IX. REPORTING RESULTS

1. If culture is negative, report final report as "No growth in x days."
2. Indicate the presence of skin flora, do not work up.
3. Report all pathogens and susceptibility tests performed.
4. Call and document any critical values as appropriate (see Critical Tests policy #2617).

X. LIMITATIONS

- Methods that employ PCR for the detection of pathogens responsible for otitis media are more sensitive than culture techniques and increase the rate of detection of a pathogen.
- False-negative cultures can result from overgrowth of the culture with normal skin flora.
- False-positive results can be caused by over interpretation of the culture results.
- *T. otitidis*, a coryneform rod, has been infrequently isolated from ear fluid and may be a cause of otitis media.
- *A. otitidis* is difficult to culture and may not be detected.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

Policy Title	ImmunoCard EHEC	Policy #	MIC131022
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

ImmunoCard STAT EHEC is an immunochromatographic rapid test for the qualitative detection of Shiga toxins 1 and 2 (also called Verotoxins) produced by *E. coli* in cultures derived from clinical stool specimens. ImmunoCard STAT EHEC is used in conjunction with the patient's clinical symptoms and other laboratory tests to aid in the diagnosis of diseases caused by enterohemorrhagic *E. coli* (EHEC) infections.

Shiga toxin producing strains of *E. coli* other than 0157 cannot be readily distinguished from nonpathogenic *E. coli* on culture. The CDC and JCAHO have mandated testing for Shiga toxin routinely on stools submitted for culture. The ImmunoCard STAT EHEC test can detect both ST1 and ST2 from broth enriched culture.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

ImmunoCard STAT EHEC Kit
Gram Negative (GN) broth

IV. STORAGE

ImmunoCard STAT EHEC is stable until the expiration date printed on the box when stored at 2-8°C. The Test Device should be used within 15 minutes after removal from the sealed foil pouch.

V. SPECIMEN

Stool specimens should be placed in modified Cary-Blair transport media within 2 hours of collection. Cary-Blair media may be stored at 2-8°C for 2-3 days.

VI. QUALITY CONTROL

Internal QC

Positive and negative internal control must be logged for each test.

- A red band at the control line constitutes the internal positive control.
- A clear background outside of the test zones indicates a valid negative internal control.

External QC

Performed with each new lot shipped and every 30 days of use.

- Five drops of positive control in the sample port should demonstrate a red band at the Toxin 1, Toxin 2 and control lines.
- Use 6 drops of Sample Diluent in the sample port for the external negative control to reveal a red band at the control line only.
- Incubate the test for 20 minutes at room temperature.
- Read results within 1 minute after the end of incubation. Record results in Log.

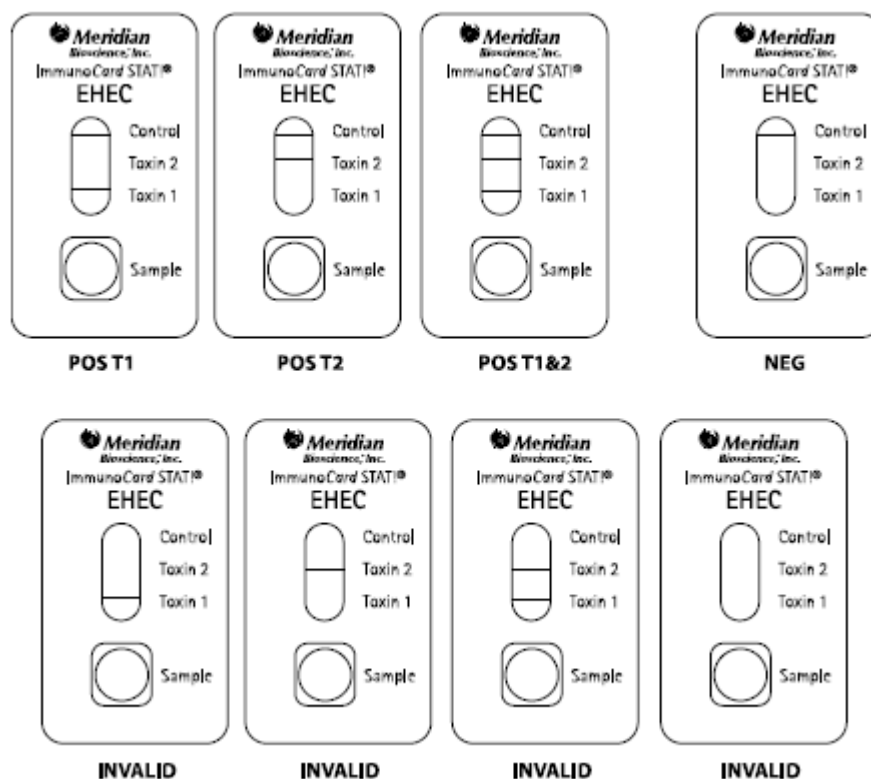
Policy Title	ImmunoCard EHEC	Policy #	MIC131022
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Lots that repeatedly fail to demonstrate the proper controls should not be used and should be referred to Meridian's Technical Services department.

VII. PROCEDURE

1. Add 175 µl of the preserved stool (mark closest to the pipet bulb) to a GN broth tube; GN broths should be incubated with the caps loose at 35°C for 16-24 hours in non-CO₂ incubator.
2. Visually inspect GN broth for growth. Broths that are not turbid (do not have growth) should not be tested.
3. Bring all Test Devices, reagents and samples to room temperature before testing.
4. Remove the ImmunoCard STAT EHEC Test Device from its foil pouch. Label the device with the patient's identification.
5. Add 5 drops of the sample diluent to a clean dry test tube.
6. Mix broth thoroughly by gently swirling the tube.
7. Using the transfer pipette supplied with the kit, add 175 µL of sample (second mark from tip of pipette) to the tube containing Sample Diluent/Negative Control.
8. Gently mix the contents of the tube with the transfer pipette by squeezing the pipette bulb 3 times.
9. Using the transfer pipette provided in the kit, slowly add 175 µL of the diluted specimen (second mark from tip of pipette) to the sample port of the device.
10. Incubate the test at 20-25°C for 20 minutes.
11. Read the results within 1 minute after the end of incubation.

VIII. INTERPRETATION



- Negative test: A PINK-RED band at the Control Line position. No other bands are present.

Policy Title	ImmunoCard EHEC	Policy #	MIC131022
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- Positive test for Shiga toxin 1: PINK-RED bands at the Control and Toxin 1 line positions. No bands at the Toxin 2 test line. The appearance of a Toxin 1 test line, even if very weak, indicates the presence of Shiga toxin 1. The intensity of the test line can be less than that of the Control line.
- Positive test for Shiga toxin 2: PINK-RED bands at the Control and Toxin 2 line positions. No bands at the Toxin 1 test line. The appearance of a Toxin 2 test line, even if very weak, indicates the presence of Shiga toxin 2. The intensity of the test line can be less than that of the Control line.
- Positive test for Shiga toxins 1 and 2: PINK-RED bands at the Control, Toxin 2, and Toxin 1 line positions. The appearance of Toxin 2 and Toxin 1 test lines, even if very weak, indicates the presence of Shiga toxins 1 and 2. The intensity of the test lines can be less than that of the Control line.
- Invalid Test Results:
 - No band at the designated position for the Control line. The test is invalid since the absence of a control band indicates the test procedure was performed improperly or that deterioration of reagents has occurred.
 - A PINK-RED band appearing at either the Toxin 1 or Toxin 2 Test Line position of the device after the defined incubation limit or a band of any color other than PINK-RED. Falsely positive results may occur if tests are incubated too long. Bands with colors other than PINK-RED may indicate reagent deterioration.

If any result is difficult to interpret, the test should be repeated with the same sample to eliminate the potential for error. Obtain a new sample and retest when the original sample repeatedly produces unreadable results.

IX. REPORTING RESULTS

- Results and QC must also be entered on the QC log sheet.
- Toxin tests that show only a red bar at the control line are negative and should be documented in the internal comments of the LIS.
- Toxin tests that fail to show the proper internal controls should not be reported.
- Toxin tests that show a red bar at either or both of the of the Toxin 1 or Toxin 2 lines should be reported as positive with canned comment EHEC (report which toxin is positive and which is negative).
- Positive toxin test should be reported as critical values and is a reportable disease.
 - Complete a CMR and fax to county of residence along with specimen results and face-sheet of patient. Keep copy along with fax confirmation page in the Microbiology Send Out binder.
 - GN broths that yield positive results should be sent to the Santa Cruz Public Health Department for confirmation (include a copy of the CMR, results and face-sheet with specimen).

X. LIMITATIONS

- The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line when reporting the result.
- Test results are to be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.
- Failure to add 175 µL of broth culture to the 5 drops of Sample Diluent/Negative Control (step 7 of SPECIMEN PREPARATION/ENRICHMENT – BROTH CULTURE) can lead to falsely negative results. As a visual aid it may be helpful to verify that the broth culture was added.

Policy Title	ImmunoCard EHEC	Policy #	MIC131022
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Mark the side of the test tube with a marking pen to indicate the top of the Sample Diluent/Negative Control volume. Once broth culture is added, this line should appear in the middle of the diluted sample volume. The addition of more than 5 drops of Sample Diluent/Negative Control can also lead to falsely negative test results.

- Over incubation of tests may lead to false-positive test results. Incubating tests at reduced temperatures or times may lead to falsely negative results.
- The performance of ImmunoCard STAT EHEC HAS NOT BEEN EVALUATED with direct stool samples. It has only been evaluated in SMAC plate culture or GN and MacConkey liquid cultures.
- NOTE: Shiga toxin 1 produced by *E. coli* and the toxin produced by *Shigella dysenteriae* type 1 strains are nearly identical. Therefore, ImmunoCard STAT EHEC may give a positive result with toxins from *S. dysenteriae* type 1 strains. The two organisms can be differentiated by plating on selective growth media coupled with biochemical analysis.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. ~~ImmunoCard~~ImmunoCard STAT EHEC 751630 Rev 01/17 Meridian Bioscience Cincinnati, OH

XII. ATTACHMENTS

ImmunoCard EHEC QC Form

F:\GROUPS\LAB\Micro\QC\Reagent QC Forms\EHEC QC Form

CMR Form

F:\GROUPS\LAB\Micro\CMR Forms\Blank CDPH CMR Form

Policy Title	Eye Culture	Policy #	MIC131023
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

The proper evaluation of an eye culture requires knowledge of the precise nature of the specimen. Conjunctival cultures are likely to be contaminated with small amounts of skin flora. Corneal ulcers collected by an Ophthalmologist may be critical with only a few organisms. Eye cultures from neonates should also be cultured for *Neisseria gonorrhoeae*.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

BAP / CHOC / MAC / TM agar plates
Glass slides
Gram stain reagent
Optochin discs
Various biochemicals and other rapid tests

IV. STORAGE

Store at room temperature until samples can be transported or processed by the laboratory. If specimen transport is delayed, store 2 - 8°C.

- A delay in processing of more than 2 hours may result in a decreased ability to recover fastidious pathogens, such as *S. pneumoniae*, *N. gonorrhoeae* and *H. influenza*, and/or overgrowth of flora.

V. SPECIMEN

Swab specimens in amies media (blue cap), corneal scrapings, aqueous or vitreous fluid in syringe (without needle).

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

Specimen Processing:

1. Process specimens as soon after receipt as possible in order to maintain the viability of the primary pathogens.
2. After the plates are set up, a gram stain slide should be made with the same swab. The slide should air dry on the heat block then be promptly stained.
3. Incubate plates at 35 to 37°C in 5% CO₂ for 48 to 72 hours.

Determining pathogens:

1. Observe plates for growth daily for a total incubation time of 72 hours.

Policy Title	Eye Culture	Policy #	MIC131023
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2. Identify the potential pathogens that grow in significant amounts and are not part of the normal skin flora (see Identification of pathogens section below for guidelines). Significant growth is defined as:
 - a. Moderate to heavy growth of an isolate in second or third quadrant of the plate.
 - b. Small amounts of a primary pathogen in the culture that is consistent with the predominant morphotype seen in the original gram stain.
3. Subculture to BAP, CHOC or MAC to obtain isolated colonies for accurate identification from mixed cultures.

Workup of Isolates:

1. Gram Negative Rods:
 - a. Perform spot indole and oxidase test. Record results in LIS
 - b. Perform GN ID and AST (GNS).
2. Staphylococci:
 - a. Perform catalase test. Record results in LIS
 1. Perform Staph latex,
 - a. If positive provide preliminary ID as *Staphylococcus aureus*. Perform AST (GPS). Perform PBP2 test if inpatient (see PBP2 policy).
 - b. If negative, report as normal skin flora
3. Streptococci and other catalase-negative cocci:
 - a. Alpha hemolytic:
 1. Heavily inoculate a BAP with well isolated alpha colony.
 2. Using sterile technique, place a P disc according to the Optochin procedure.
 3. Incubate at 35°C overnight in CO₂ incubator.
 - a. If no zone around P disc, report as normal respiratory flora.
 - b. If zone around P disc ≥ 14mm, provide preliminary ID as presumptive *Streptococcus pneumoniae*. Perform confirmatory GP ID and AST (STO2).
 - c. If zone around P disc is between 6 and 14mm, perform bile solubility (see Bile Solubility 2176) and confirmatory GP ID and AST (STO2).
 - b. Beta hemolytic:
 1. Perform catalase, should be negative, record results in LIS
 2. Perform Strep typing, record results in LIS
 3. Provide preliminary result with organism name or Lancefield group.
 4. Set up AST (STO2).
 - c. Enterococci (gamma hemolytic)
 1. Perform catalase, should be negative or weakly positive, record results in LIS
 2. Perform PYR, should be positive, record results in LIS
 3. Provide preliminary result as "Gamma Streptococcus, usually *Enterococcus* species, ID to follow."
 4. Set up GP ID and AST (GPS).
4. Gram Positive Rods:
 - a. Examine for large, spore-forming gram positive rods, if present perform ANC ID to rule out *Bacillus anthracis* and *Bacillus cereus*.

Policy Title	Eye Culture	Policy #	MIC131023
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- b. Generally, do not pursue other gram positive rods, as they are unlikely to cause pneumonia.
5. Gram Negative Coccobacilli and Diplococci:
 - a. Perform oxidase test, record results in LIS
 - b. Set up NH ID.
 - c. If organism is *H. influenzae*, perform beta-lactamase test (see Cefinase Disc policy), record results in LIS and include in final report.
6. Yeast:
 - a. Review gram stain to confirm yeast seen, record results in LIS.
 - b. If insufficient growth on BAP, sub to SAB and incubate in fungus or CO₂ incubator.
 - c. If sufficient growth on BAP and yeast has "feet"_{7,8}, report as presumptive *Candida albicans*. If no feet, report preliminary result as "Yeast species, ID to follow."
 - d. Set up Yeast ID.

Common Normal Flora:

Coagulase negative staphylococci

Viridans group streptococci

Corynebacterium

P. acnes

Common Pathogens:

Haemophilus influenzae

Streptococcus pneumoniae

Staphylococcus aureus

Beta Streptococcus

Gram negative rods

Neisseria gonorrhoeae

Moraxella spp.

VIII. INTERPRETATION

1. All organisms grown in any amount from critical eye specimens (aqueous and vitreous fluid) should be identified and have susceptibilities performed.
2. All organisms present in the gram stain that grows on primary plates are considered clinically significant and should be worked up.
3. The following criteria will help determine the clinical significance of bacterial isolated from critical eye specimens that may otherwise be considered normal flora:
 - a. Isolates of coagulase negative staphylococci, diphtheroids, *P. acnes*, or viridans group streptococci that grow on more than one medium are generally considered significant.
 - b. Normal flora may also be clinically significant when growth occurs on only one medium. In these cases, a comment may be added to the final report indicating that the clinical significance of organisms that are part of the skin microbiota must be determined by the clinical picture.

Policy Title	Eye Culture	Policy #	MIC131023
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IX. REPORTING RESULTS

1. Semi-quantitate growth (Rare or Scant, Light, Moderate or Heavy) along with the genus and species of each organism identified. Report AST as appropriate.
2. Call and document any critical values as appropriate (see Critical Tests policy #2617).

X. LIMITATIONS

- False-positive cultures can result from contamination of the specimen or the inoculated plates with skin microbiota.
- False-negative cultures can result from considering corynebacteria as contaminating microbiota when they can be pathogens. For example, *Corynebacterium macginleyi* has been implicated in conjunctivitis and corneal ulcers.
- False-negative results can occur if antimicrobial agents are given prior to collection of the specimen.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

Policy Title	Fecal Leukocyte Stain	Policy #	MIC131024
Responsible	Laboratory Director	Revised/Reviewed	01/2021 12/15/2022

I. PURPOSE

Fecal leukocytes are found in patients with Shigellosis, Salmonellosis, Campylobacter, invasive Escherichia coli colitis, and idiopathic ulcerative colitis. Finding WBC in stool specimens may be helpful in determining the need for antibiotic treatment before culture results are available. The Methylene Blue wet prep is a more sensitive test than gram staining due to the fragile state of the white cell wall in stool specimens and the increased volume of material examined in a wet prep.

II. POLICY

The Methylene Blue wet mount stain will be our primary method for determining the presence of WBC in stool specimens. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Glass slide and cover slip
Loefflers Methylene Blue stain
Applicator stick

IV. STORAGE

Store Methylene blue stain at 2 - 30°C. Use until expiration date printed on bottle.
Store stool at room temperature for up to 2 hours. After 2 hours, place stool in 10% formalin and/or polyvinyl alcohol (PVA). Preserved stool may be stored indefinitely.

V. SPECIMEN

Unpreserved, fresh stool or stool that has been placed in 10% formalin and/or PVA.

Rejection Criteria:

Reject fresh (unpreserved) stool delayed in transport and received more than 2 hours after collection.

VI. QUALITY CONTROL

The stain should appear dark royal blue in color. Product should not be used if there are any signs of deterioration or if the expiration date has passed. Do not expose to excessive heat or moisture.

Controls should be run each day of use.

Negative control:

1. Add one drop of saline to 1 drop of methylene blue, cover with coverslip.
2. Scan slide using 40x. No bacteria or cells should be visible
3. Record results in day of use log.

Positive control:

Policy Title	Fecal Leukocyte Stain	Policy #	MIC131024
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1. Add one drop of buffy coat from an EDTA blood sample to 1 drop of methylene blue, cover with coverslip.
2. Scan slide using 40x. Cellular components should be seen.
3. Record results in day of use log.

VII. PROCEDURE

1. Place a drop of liquid feces or a small fleck of mucus on a glass slide.
2. Add two drops of stain and mix thoroughly and add a cover slip.
3. Let slid stand for 2 – 3 minutes.
4. Scan slide using 20x and confirm results on 40x.

VIII. INTERPRETATION

The threshold for positivity of fecal leukocytes is not clear, with different authors suggesting >1 WBC / 40x or >5 WBCs / 40x. Regardless, the sensitivity is poor, ranging from 52 to 63%.

IX. REPORTING RESULTS

Semi-quantify WBCs seen per 40x.

0	No WBCs seen
≤ 1	Few WBC seen
1 – 4	Moderate WBCs seen
≥ 5	Many WBCs seen

X. LIMITATIONS

Activated leukocytes disintegrate easily, decreasing the sensitivity of the assay with delays in transit.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. Methylene Blue, Loefflers. Instructions for Use, Hardy Diagnostics
https://catalog.hardydiagnostics.com/cp_prod/Content/hugo/MethyleneBlueLoefflers.htm

XII. ATTACHMENTS

Reagent Daily or Day of Use Form
(F:\GROUPS\LAB\Micro\Checklists\CLS\Reagent Daily or Day of Use Form)

Policy Title	Genital Culture	Policy #	MIC131026
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

Specimens from genital sites are sent to the clinical microbiology laboratory for detection of microorganisms from females presenting with clinical syndromes such as cervicitis, vulvovaginitis, urethritis, bacterial vaginosis (BV), pelvic inflammatory disease (PID), endometritis or genital ulcers, and from males exhibiting urethritis, epididymitis, prostatitis or genital ulcers.

Common organisms colonizing the female genital tract include lactobacilli, *Corynebacterium* spp., *Gardnerella vaginalis*, coagulase-negative staphylococcus, *Enterococcus* spp., enteric gram negative rods and anaerobes.

Common potential pathogens include (but not limited to) *Streptococcus agalactiae*, *Staphylococcus aureus*, *Neisseria gonorrhoeae*, *Streptococcus pyogenes*, *Candida* spp.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

- BAP
- CHOC
- MAC
- TM
- V Agar (not for vaginal specimens)
- Selective Strep Agar
- Catalase
- Oxidase

IV. STORAGE

Specimens should be set up as soon as possible once received in the laboratory. Specimens may be stored 2-8°C if there is a delay in set up.

V. SPECIMEN

Acceptable sources for genital cultures include cervix, endocervical, vagina, Bartholin cyst, vulva, epididymitis or testicular abscess, penile lesion or vesicle, prostate, urethra, other abscesses or lesions found in the genital area.

VI. QUALITY CONTROL

Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

VII. PROCEDURE

Policy Title	Genital Culture	Policy #	MIC131026
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1. Observe plates for growth of abnormal microbiota.
2. Identify the following pathogens, if present:
 - a) Examine non-lactose fermenting gram negative rods for *Shigella* or other enteric pathogens. ** Note: do not examine cervical or vaginal specimens for other *Enterobacteriaceae*, as these organisms are normally found in the female genital tract.
 - b) *Streptococcus pyogenes*
 - c) *Streptococcus agalactiae*
 - d) *Listeria monocytogenes*
 - e) *Neisseria gonorrhoeae*
 - f) *Candida albicans* or other yeast
3. Identify the following only if the specimen was invasively collected or there is heavy growth and they are the predominant organism in the culture.
 - a) *Haemophilus* spp
 - b) Gram negative rods (exception: *Enterobacteriaceae* are part of the normal microbiota of the vagina and should not be reported)
 - c) *Pseudomonas* spp. and other non-fermenting gram negative rods
 - d) *Staphylococcus aureus*
 - e) *Streptococcus pneumoniae*
 - f) *Neisseria meningitidis*
 - g) *Gardnerella vaginalis*

** NOTE: for vaginal specimens, **do NOT set use selective medium to isolate this organism**, because the importance of its isolation is determined by the quantity compared to that of lactobacilli in the culture. *G vaginalis* grows well on CHOC. When present in quantities less than the other normal microbiota, it should be included as part of normal vaginal flora. However, for children report its presence regardless of quantity present. **If it is the predominant organism from the female vaginal tract and is isolated in 3+ to 4+ quantities (third or fourth quadrant), report its presence.
 - i. Identification
 1. Colonies appear pinpoint and transparent
 2. Gram variable to gram negative small, pleomorphic coccobacilli that do not elongate into filaments or chains
 3. Catalase negative.
4. Susceptibility testing
 - a) AST should be performed on all aerobic bacteria isolates from pelvic or amniotic fluid or tissue specimens that are considered to be primary pathogens.
 - b) *N. gonorrhoeae* isolated from any genital site should be referred for anti-microbial susceptibility testing.
 - c) Fastidious gram negative coccobacilli or rods that do not grow on MAC should have beta-lactamase test.

VIII. INTERPRETATION

1. The presence of any organism from a normally sterile site is generally considered significant.
2. Isolation of sexually transmitted disease pathogens (e.g., *N. gonorrhoeae* and *H. ducreyi*) is considered clinically significant from any genital site. Isolation of certain organisms such as *S. pyogenes* and *C. perfringens* from soft tissue as well as endometrial tissue or transvaginal fluid samples should also be considered clinically significant.
3. The presence of other pathogens may or may not be a cause of disease and must be evaluated with consideration of relative amounts and symptoms or other conditions (e.g., pregnancy) in the patient.

Policy Title	Genital Culture	Policy #	MIC131026
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IX. REPORTING RESULTS

1. Semi-quantitate growth (Rare or Scant, Light, Moderate or Heavy) along with the genus and species of each organism identified. Report AST as appropriate.
2. Call and document any critical values as appropriate (see Critical Tests policy #2617).

X. LIMITATIONS

- Many agents of disease are difficult to culture, and the lack of isolation may not indicate that the pathogen is not the cause of disease.
- Communication between the laboratory and the physician is necessary to provide the appropriate cultures for the disease present, since agents such as *H. ducreyi* may not grow on routine laboratory media.
- Group B beta Strep. is generally considered normal flora when isolated from the external female genital tract but can lead to life threatening infections if passed to neonates. It should therefore be ruled out in all women of child bearing age. Unless selective media and incubation are used, a routine genital culture will not detect carriage of GBS in all cases.
- BV is bets diagnosed by gram stain using Nugent's criteria.
- The presence of fastidious gram negative rods in genital specimens may or may not indicate infection. Cases have been reported, but they are infrequent.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. STAKEHOLDERS

N/A

Policy Title	Germ Tube	Policy #	MIC131027
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

This test is a rapid presumptive test for the identification of *Candida albicans*.

II. POLICY

Germ Tube test will be performed on yeast of significance to aid in their identification. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Sterile Serum

Test tubes

Candida albicans ATCC 14053

IV. STORAGE

An isolate of *C. albicans* ATCC 14053 will be maintained in the Weekly QC can stored 2-8°C

V. SPECIMEN

Suspected yeast colonies – without “feet.”

VI. QUALITY CONTROL

Positive and negative controls are to be run with each patient test. Record results in the Reagent Daily or Day of Use Form. Verify that media meets expiration date and QC parameters per Microbiology Policies MIC.131.018 and MIC.131.047.

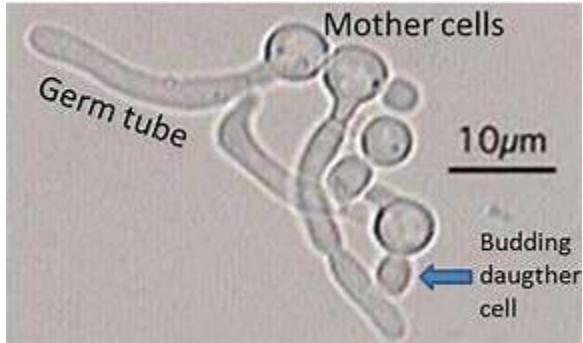
Positive Control: *C. albicans*

Negative Control: Serum without yeast

VII. PROCEDURE

1. Lightly touch a yeast colony with a wooden applicator stick.
2. Suspend the yeast cells in a tube with 0.5 ml serum.
3. Incubate at 35-37°C for 2.5 to 3 hours.
4. Place a drop of the suspension on a glass slide and cover with coverslip
5. Examine for the presence or absence of germ tubes. A germ tube appears as a short lateral extension from the yeast cell and does not have a constriction (septum) where it meets the yeast cell or any constriction at the septum along the tube. In a true germ tube, the first septum produced by a germinating cell is located along the tube near the point of juncture with the parent cell but not at the juncture. A constriction where the lateral extension meets the yeast cell is produced by pseudohyphae or budding cells. A minimum of five germ tubes should be observed before the isolate is called positive.

Policy Title	Germ Tube	Policy #	MIC131027
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VIII. INTERPRETATION

Germ tubes present indicated presumptive identification of *Candida albicans*. Absence of germ tubes indicates *Candida* species, not *albicans*, further work up may be indicated.

IX. REPORTING RESULTS

Record results in LIS.

X. LIMITATIONS

- Sabouraud dextrose agar (SAB) is the best medium to isolate yeast for germ tube production; sheep blood agar (BAP) is an acceptable substitute.
- Some *C. tropicalis* isolates produce pseudohyphae and some also produce germ tubes that require careful observation to discriminate from those of *C. albicans*.
- Frequently, isolates of *C. albicans* produce colonies described as "yeasts with feet" in recognition of peripheral fringe. This occurs most commonly on serum enriched media (BAP). These colonies should not be used for the germ tube test, because cells within the colony have produced pseudohyphae and germ tubes.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

Reagent Daily or Day of Use Form

F:\GROUPS\LAB\Micro\Checklists\CLS\Reagent Daily or Day of Use Form

Policy Title	Indole	Policy #	MIC131030
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

The indole test is a rapid adaptation to standard tube methodology. Care must be taken to pick colonies only from plate media that contains tryptophan (such as a blood agar plate). Although several organisms can give a positive indole reaction, the most notable is *E. coli*. A positive indole test can help support a presumptive identification of *E. coli* (along with appropriate colony morphology). A spot indole test in combination with an oxidase test is also helpful in screening stool cultures for *Vibrio* and *Aeromonas* species.

II. POLICY

Indole reagent is recommended for use in determining the indole reaction of bacteria. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Indole Kovacs reagent
Wooden stick

IV. STORAGE

Store at 2 - 30°C. The product may be used and tested up to the expiration date on the label.

V. SPECIMEN

Fresh growth of a gram negative rod on BAP or CHOC

VI. QUALITY CONTROL

QC should be performed each day of use; *E. coli* (ATCC 29522) will give a positive reaction and *P. aeruginosa* (ATCC 27853) will give a negative reaction. Record results on the Reagent Daily or Day of Use QC Form. Do not use if color is not pale yellow.

VII. PROCEDURE

1. Place a drop of Kovacs reagent on a piece of white filter paper.
2. Sweep a portion of the colony using a wooden stick and place on paper
3. Observe the smear for any color change.

VIII. INTERPRETATION

The development of red to purple-brown color within 20 seconds indicated the presence of indole. A negative test is colorless or slightly yellow.

IX. REPORTING RESULTS

Record result in LIS as indole positive (ind+) or indole negative (ind-).

Policy Title	Indole	Policy #	MIC131030
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X. LIMITATIONS:

- Detectable indole will diffuse to colonies within 5mm of a 2 to 3 mm colony giving false positive results.
- Growth on medium must contain an adequate amount of tryptophan. Do not use Mueller-Hinton agar for test, because tryptophan is destroyed during the acid hydrolysis of casein.
- Only the cinnamaldehyde reagent can be used for spot testing of anaerobic organisms. It is the more sensitive reagent, but it is less stable.
- Do not use a plate with a nitrate disk to perform the indole test, as nitrate can interfere with the spot indole test by inducing false negative results.
- If the rapid indole test is negative, the isolate could be positive in the more sensitive tube test. Extraction with xylene is the most sensitive test. Xylene substitutes are less sensitive.
- For fastidious gram negative rods, such as *C. hominis*, a heavy inoculum and extraction are necessary.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

Reagent Daily or Day of Use Form

F:\Micro\QC\Reagent QC Forms\Reagent Daily or Day of Use Form

Policy Title	KOH	Policy #	MIC131032
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

Microscopic examination may provide a rapid indication of the cause of an infection, allowing the prompt initiation of appropriate antifungal therapy. Potassium Hydroxide (KOH) is used in a rapid method for distinguishing fungal elements in microscopic preparations. KOH is useful when examining mucoid specimens or material containing keratin, such as skin, scales, nails, or hair. KOH digests mucous and keratin, clearing the background and making fungal elements more visible.

II. POLICY

Potassium Hydroxide (KOH) is recommended for use in slide preparations of specimens for the purpose of identifying fungal elements. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Potassium hydroxide (KOH) 20%
Glass slide and cover slips

IV. STORAGE

Upon receipt store at 15-30°C. Products should not be used if there are any signs of contamination, deterioration, or if the expiration date has passed.

V. SPECIMEN

Hair, skin scrapings, nail clippings. Samples should be collected using sterilized equipment and aseptic technique to minimize contamination

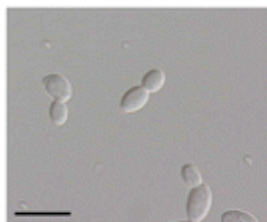
VI. QUALITY CONTROL

Examine routinely for contamination, deterioration or discoloration. Potassium hydroxide should appear clear and colorless

VII. PROCEDURE

1. Place a drop of Potassium Hydroxide (KOH) in the center of a clean slide.
2. Mix a portion of the specimen in the drop of solution.
3. Cover with a coverslip and press gently to make a thin mount. Gentle warming may aid in clearing the mount.
4. Examine under low power (10x) with low light intensity. Look for fungal structures such as hyphae or yeast. If any look suspicious, use the high-dry objective (40x) to investigate further, as hyphae or budding yeast suggest the presence of fungus.

Policy Title	KOH	Policy #	MIC131032
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Yeast



Pseudohyphae



Hyphae

<https://ec.asm.org/content/10/9/1173/figures-only>

VIII. INTERPRETATION

Positive results: Fungal elements can be observed under microscope. Different fungal elements like hyphae, pseudohyphae, yeast cells, spores, spherules and sclerotic bodies can be seen clearly in a KOH wet mount.

Negative results: None of the fungal structures is found on the entire slide.

IX. REPORTING RESULTS

Enter results in LIS:

- No fungal elements seen
- Fungal elements seen (describe elements, i.e., yeast cells, hyphae, pseudohyphae, etc.)

X. LIMITATIONS

- Potassium hydroxide is useful in the recognition and presumptive identification of fungi. Additional characteristics including colony morphology and biochemical tests should be used where appropriate for final identification.
- Prolonged exposure of a mold to KOH may result in distortion of the fungal elements.
- The slide preparation should be stored in a moist chamber prior to reading to avoid drying.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. Potassium Hydroxide (KOH) Solutions, Hardy Diagnostics. Instructions for Use:
https://catalog.hardydiagnostics.com/cp_prod/Content/hugo/PotassiumHydroxideSolns.htm

XII. ATTACHMENTS N/A

Policy Title	MIO Media	Policy #	MIC131040
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/18/2022

I. PURPOSE/PRINCIPLE

Motility Indole Ornithine (MIO) Medium is used to demonstrate motility, indole production and ornithine decarboxylase activity for the differentiation of *Enterobacteriaceae*.

The casein and gelatin peptones, yeast extract and dextrose provide nitrogenous and carbonaceous substances, vitamins and minerals essential for bacterial metabolism. When ornithine decarboxylase is present, the ornithine is decarboxylated to putrescine which causes a rise in the pH and corresponding color change of the bromcresol purple from yellow to purple.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

MIO media
Kovacs' reagent (indole)

IV. STORAGE

On receipt, store tubes in the dark at 2–25°C. Avoid freezing and overheating. Do not open until ready to use. Minimize exposure to light. Tubed media stored as labeled until just prior to use may be inoculated up to the expiration date and incubated for the recommended incubation times.

V. SPECIMEN

Well isolated non-lactose fermenting colonies from stool culture.

VI. QUALITY CONTROL

Each lot of MIO media is tested upon receipt with *E. coli* #25922 and *K. pneumoniae* #33495. See the Media QC Procedure.

VII. PROCEDURE

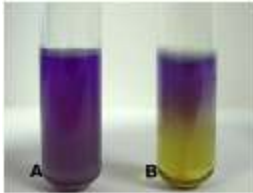
- With a sterile inoculating loop or needle touch one well isolated colony from an overnight growth plate.
- Stab the loop straight down into the media about half the length of the tube and pull it straight back out.
- Put the cap back on loosely and incubate the tube at 35°C in a non-CO₂ incubator for 18 - 24 hours.
- After incubation, observe and record reactions for motility and ornithine prior to adding 3 – 4 drops of Kovacs' reagent.

VIII. INTERPRETATION

Read motility and decarboxylase activity prior to the addition of the reagent for the detection of indole production.

Policy Title	MIO Media	Policy #	MIC131040
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- Motility: Positive motility is indicated by growth extending from the line of inoculation. Non-motile organisms grow only along the line of inoculation.
- Ornithine: Positive result is indicated by the development of a turbid purple to a faded yellow-purple color (see A in photo below). Negative reaction is indicated by a yellow color (see B in photo below).



<https://www.studyblue.com/notes/n/lab-practical-2/deck/14047546>

- Indole production is indicated by the formation of a pink to red color after the addition of three or four drops of Kovacs' reagent to the surface of the medium and gentle shaking. A negative reaction is indicated by the development of a yellow color.

IX. REPORTING RESULTS

1. These reactions should be recorded as + or - in the internal comment screen of the LIS.
2. Proceed with culture as indicated on the Possible Stool Pathogen Flow Sheet.

X. LIMITATIONS

An accurate Ornithine reaction requires that the organism can grow in the media and has had sufficient time to first acidify and then to raise the pH sufficiently to revert the indicator back to purple. If growth is not observed along the stab line, the test is not valid. This is most often observed with *Pseudomonas* and other obligate aerobic bacteria that are unable to grow below the surface of the agar.

XI. REFERENCES

1. BBL™ Motility Indole Ornithine (MIO) Medium, L007472 Rev. 10 January 2015, Becton Dickinson, Sparks MD

XII. ATTACHMENTS **N/A**

Policy Title	MRSA Latex Agglutination	Policy #	MIC131041
Responsible	Laboratory Director	Revised/Reviewed	<u>12/15/2022</u> 01/2024

I. PURPOSE

Early detection of methicillin-resistant Staphylococcal infections is known to reduce health care costs, critical in efforts to decrease patient morbidity and mortality, reduce empiric use of vancomycin and permits cost-effective decisions for optimal patient management.

The Alere PBP2a SA Culture Colony Test is a rapid immunochromatographic membrane assay that uses highly sensitive recombinant monoclonal antibody fragments (rFabs) to detect the PBP2a protein directly from bacterial isolates. The rFab and a control protein are immobilized onto a nitrocellulose membrane as two distinct lines and combined with a sample pad, a pink/purple conjugate pad, and an absorption pad to form a test strip.

Isolates are sampled directly from the culture plate and eluted into an assay tube containing Reagent 1. Reagent 2 is then added and the test strip is placed in the assay tube. Results are read visually at 5 minutes.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Materials provided in the PBP2 kit:

- Test Strip
- Reagent 1
- Reagent 2
- Assay Tubes
- Test Rack

IV. STORAGE

Store kit at 2-30°C. Allow all components to come to room temperature prior to use. Kit and reagents are stable until the expiration date marked on the packaging.

V. SPECIMEN

Specimens are bacterial isolates of *Staphylococcus aureus*. The use of fresh (<24 hours) cultures is recommended. Colonies are tested from BAP, CNA and Mueller Hinton agars.

VI. QUALITY CONTROL

Internal Procedural Controls:

The kit has built-in positive and negative procedural controls (internal controls).

- The appearance of a pink/purple line at the “control line” position can be considered an internal positive procedural control. If capillary flow has occurred, this line will always appear.

Policy Title	MRSA Latex Agglutination	Policy #	MIC131041
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- In comparison to the color of the control line, the background color on the test strip should be white within 5 minutes; this can be considered an internal negative procedural control.

External Controls:

For each new lot / shipment, external positive and negative controls must be run prior to use. These will monitor the entire assay. The results of these control samples will be recorded in the Alere PBP2a QC Form found in the Micro QC binder.

- Positive control: *Staphylococcus aureus* ATCC 43300
- Negative control: *Staphylococcus aureus* ATCC 29213

VII. PROCEDURE

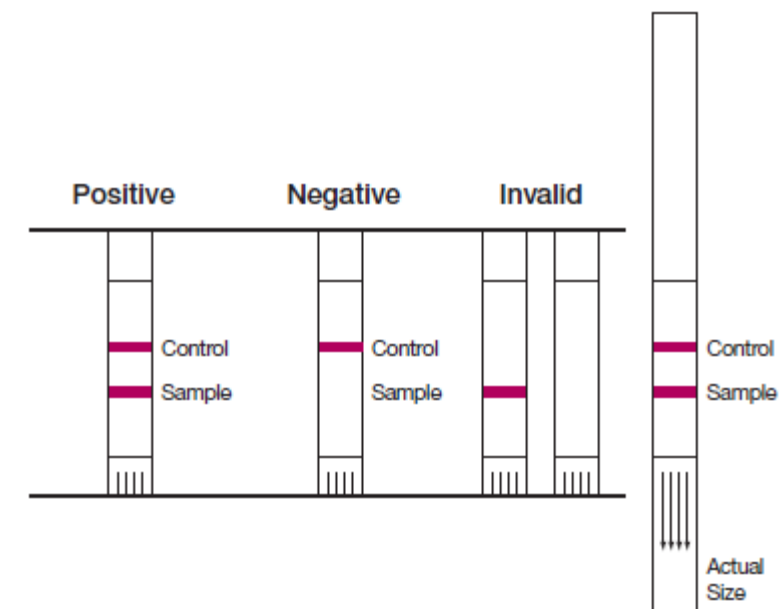
Allow reagents to equilibrate to room temperature prior to testing.

1. Holding the dropper bottle vertically, add two drops of Reagent 1 to an assay tube.
2. Take one heaped 1µl loop (a heavy inoculum) of sample from well-isolated colonies on the culture plate and place into the tube. Mix thoroughly.
3. Holding the dropper bottle vertically, add two drops of Reagent 2 to the tube. Mix well (the blue solution will turn clear).
4. Insert the test strip into the assay tube with arrows pointed downward.
5. Read at 5 minutes. Record results in LIS

VIII. INTERPRETATION

- **Negative result:** Pink/purple control line appears in the top half of the test strip; no other lines visible.
- **Positive result:** Pink/purple control line appears and a second pink/purple sample line appears below the control line (bottom half of the strip). Any sample line, even when very faint, is positive.
- **Invalid result:** Pink/purple control line does not appear, even if sample line is present. Repeat invalid tests with new test strip. Call Alere Technical Support if problem persists.

Policy Title	MRSA Latex Agglutination	Policy #	MIC131041
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Reporting of Results

Result	Suggested Report
Positive	Positive for PBP2a
Negative	Negative for PBP2a
Invalid	Indeterminate; do not report. Re-test sample and contact Alere™ Technical Service Support if problem persists.

IX. REPORTING RESULTS

Record result in LIS as PBP+ (positive) or PBP- (negative). Confirm results with GP AST. MRSA is considered to be a critical value. Call and document critical value per Critical Test policy 2617.

X. LIMITATIONS

- Rare *Staph. aureus* isolates have been found to possess borderline methicillin resistance due to the hyper-production of beta lactamase or MOD. These strains may test negative with the latex agglutination test but their therapeutic response to beta lactams is uncertain.
- *Staph.* other than *Staph. aureus* may possess the *mecA* gene and may test positive with this test but often require induction for sufficient PBP2 production to give a positive reaction. Non-*mecA* methods of resistance are also more common in these organisms.
- Caution must be used to avoid reporting MRSA latex results on coagulase negative *Staph* or contaminated *Staph. aureus* isolates.
- Failure to use a large enough inoculum or to rock the card for a full three minutes may reduce the sensitivity of the test.
- If discrepancies between the MRSA latex test and MIC testing cannot be resolved, the isolate should be reported as resistant.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. Alere PBP2a SA Culture Colony Test. Package Insert. 893-000 v. 4.0

Policy Title	MRSA Latex Agglutination	Policy #	MIC131041
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XII. ATTACHMENTS

Alere PBP2a QC Form

F:\Micro\QC\Reagent QC Forms\Alere PBP2a QC Form

Policy Title	MRSA Screen	Policy #	MIC131042
Responsible	Laboratory Director	Revised/Reviewed	08/14/2020 10/18/2022

I. PURPOSE/PRINCIPLE

MRSA is a major cause of nosocomial and life threatening infections. MRSA infections have been associated with a significantly higher morbidity, mortality and cost compared to methicillin-susceptible *S. aureus* (MSSA) infections. Selection of these organisms has been greatest in the healthcare setting; however, MRSA has also become more prevalent in the community.

To control the transmission of MRSA, the Society for Healthcare Epidemiology of America (SHEA) has published guidelines, which include an active surveillance program to identify potential reservoirs and a rigorous infection control program to control the spread of MRSA.

II. POLICY

Remel Spectra MRSA is an opaque medium, which uses a novel chromogen that yields a denim blue color as a result of phosphatase activity. This enzyme is present in all MRSA. To allow the medium to differentiate MRSA accurately, it contains a combination of antibacterial compounds designed to inhibit the growth of a wide variety of competitor organisms. Also included are compounds that encourage the production of MRSA pathogenicity marker, ensuring expression of the phosphatase enzyme and so providing enhanced sensitivity and specificity. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Spectra MRSA agar
Catalase
Staph Latex Agglutination
Glass slides
Gram Stain Reagents

IV. STORAGE

Spectra MRSA agar should be stored at 2-8°C. Plates are good until the expiration date listed on packaging and stamped on plates.

V. SPECIMEN

Acceptable MRSA sites: nares, axilla and groin. Acceptable sites should be swabbed with the same swab and placed in aerobic transport media for shipment to the lab.

VI. QUALITY CONTROL

Each lot of media needs to be tested for positive and negative reactions. Staph. aureus ATCC 43300 should produce denim blue colonies in 24 hours. Staph. aureus ATCC 29213 should not grow individual colonies but may yield blue agar. Fresh isolated colonies should be used and will be streaked onto half of a plate and incubated at 35°C. in non-CO₂ incubator. See Commercially Prepared Media QC policy MIC.131.018 for further instructions.

Policy Title	MRSA Screen	Policy #	LAB131042
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VII. PROCEDURE

Specimen Processing:

1. Role the swab over the main inoculum area and streak the plate for isolation. Write the time and date on the plate and place it in the 35°C non-CO₂ incubator.

Determining pathogens:

1. After 24 hours of incubation, observe plate for growth. Colonies of MRSA will appear denim blue on the agar. Other organisms (non-MRSA) will be inhibited or produce white to colorless colonies, some Staph species may turn the agar blue but no individual colonies are observed.
2. Blue colonies should be confirmed as catalase positive, gram positive cocci that are Staph latex positive prior to reporting as MRSA. All testing documentation to be recorded in the LIS.

VIII. INTERPRETATION

The growth of blue color colonies that are also catalase positive, gram positive cocci and Staph latex positive may be reported as MRSA.

IX. REPORTING RESULTS

Report in the LIS, use code "MRSAS":- Change result to "Positive" if screen is positive for MRSA. Call and document the critical results on in-patients per Critical Test policy 2617.

X. LIMITATIONS

- Organisms with atypical enzyme patterns may give anomalous results.
- Incubation in CO₂ may reduce recovery and potentially result in a false negative reaction.
- The growth requirements of certain MRSA can lead to their partial or complete inhibition in culture. A false-negative MRSA result may occur when testing borderline oxacillin-resistant strains of *S. aureus* (BORSA) or modified *S. aureus* (MODSA). These strains have oxacillin MICs of 4-8 µg/ml.
- Surveillance testing determines the colonization status at a given time and can vary depending on patient treatment, patient status (actively shedding), or exposure to high-risk environments. Monitoring of colonization status should be performed in accordance with hospital policies and procedures.
- Neutralization of antimicrobial activity by dilution in the blood culture media varies depending on the dosage level, susceptibility of the microorganism, and timing of specimen collection. The use of supplementary additives should be considered in appropriate situations. Users should be cognizant of manufacturer information for Blood Culture systems regarding the recovery of microorganisms.
- The performance of Spectra MRSA has not been established for blood culture bottle types other than those shown in the Instructions for Use.
- The performance of Spectra MRSA when testing pediatric blood cultures is unknown because insufficient pediatric samples were evaluated and none were positive for MRSA.
- In preclinical recovery studies conducted with low inoculum, a fewer number of colonies than expected were observed for the heteroresistant MRSA (ATCC 43300). The observation was most notable for VersaTrek Redox 1 and Redox 2 blood culture bottles. The reasons for this observation are not known.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

Policy Title	MRSA Screen	Policy #	LAB131042
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2. Remel Spectra MRSA, Instructions for Use 1821, April 16, 2013

XII. ATTACHMENTS

N/A

Policy Title	Optochin Disc	Policy #	MIC131043
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

Optochin discs are impregnated with ethylhydrocupreine hydrochloride (optochin), a drug used for pneumonia therapy before sulfonamides became available. The growth of pneumococci, but not of other streptococci, is markedly inhibited by this chemical. Pneumococci may, therefore, be differentiated from other alpha-hemolytic streptococci by the formation of a zone of inhibition around a P disc placed on a blood agar plate heavily inoculated with a pure culture suspected to be *Streptococcus pneumoniae*. A positive identification in an organism with gram stain and colony morphology consistent with *S. pneumoniae* is made when a well-defined zone of inhibition forms around the impregnated disk. Other alpha-hemolytic streptococci do not display this clear zone of inhibition in the presence of optochin.

II. POLICY

Optochin susceptibility will be used as our primary means of screening for *S. pneumoniae*. Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Optochin Taxo Discs (P discs)
BAP agar

IV. STORAGE

Store Optochin disc at -20 to 8°C until opening container. After cartridge is opened, store 2 -8°C. Allow to come to room temperature prior to use.

V. SPECIMEN

The discs are not for use directly with clinical specimens or other sources containing mixed flora..

VI. QUALITY CONTROL

Perform QC prior to use of new lots / shipment, weekly QC is also performed (set up on Sunday, read on Monday). QC results are to be recorded in the Micro QC binder. Positive organism demonstrates zone formation (14mm or larger in diameter); negative organism demonstrates no zone formation.

Positive organism: *S. pneumoniae* ATCC 6305

Negative organism: *S. pyogenes* ATCC 12384

Verify that media meets expiration date and QC parameters per Microbiology Policies 2126 and 2156.

VII. PROCEDURE

1. Heavily inoculate a BAP with well isolated alpha colony.
2. Using sterile technique, place a P disc according to the Optochin procedure.
3. Incubate at 35°C overnight in CO₂ incubator.
 - a. If no zone around P disc, report as normal respiratory flora.

Policy Title	Optochin Disc	Policy #	MIC131043
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- b. If zone around P disc ≥ 14 mm, provide preliminary ID as presumptive *Streptococcus pneumoniae*. Perform confirmatory GP ID and AST (STO2).
- c. If zone around P disc is between 6 and 14mm, perform bile solubility (see Bile Solubility MIC.131.006) before reporting as presumptive *Streptococcus pneumoniae*.

VIII. INTERPRETATION

1. A zone on inhibition of ≥ 14 mm around the disc is considered a susceptible result, therefore, the organism is considered to be *Streptococcus pneumoniae*.
2. Organisms with zone sizes of < 14 mm around the disc should be considered intermediate in susceptibility to optochin. Perform ID with GP ID card.
3. If there is no zone around the disc, the organism is considered resistant to optochin, therefore, not *Streptococcus pneumoniae*.

IX. REPORTING RESULTS

- Report an identification of presumptive *S. pneumoniae* if the alpha-hemolytic colony from gram positive cocci in pairs is catalase negative and susceptible to optochin. Confirm ID with GP ID card.
- If the organism is optochin resistant, catalase negative, alpha-hemolytic and gram positive cocci in pairs, report as viridans group streptococcus or flora, if appropriate for specimen source.

X. LIMITATIONS

- *S. pneumoniae* isolates should be incubated in a CO₂ enriched environment, as some isolates will grow poorly or not at all without increased CO₂.
- If the organism is optochin resistant, it is likely to be a non-pneumococcal alpha-hemolytic streptococcus; however, rare exceptions have been reported.
- Optochin susceptibility is an excellent test to identify *S. pneumoniae*, with a 99% sensitivity for *encapsulated* strains and 98% to 99% specificity. However, Mundy et al. (2) reported that only 10 of 33 non-encapsulated strains positive by DNA probe were detected as susceptible by optochin; the remainder had intermediate zone diameters with optochin.
- If there are colonies present within the zone on inhibition, these colonies may or may not be pneumococci. Resistant strains may exhibit this phenomenon; however, it is rare. True optochin-resistant strains have only been reported in three cases. The resistance was shown to be a point mutation in strains from patients that had been treated with antimicrobial agents. Subculture such colonies and confirm with gram stain, catalase test and bile solubility to determine if they are contaminants or pneumococci prior to reporting susceptibility results.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. BD BBL Taxo P Discs for Differentiation of Pneumococci. 2015-04
3. Mundy LS, Janoff EN, Schwebke KE, Shanholtzer CJ, Willard KE. 1998. Ambiguity in the identification of *Streptococcus pneumoniae*. Optochin, bile solubility, quelling, and the AccuProbe DNA probe tests. *Am J Clin Pathol* 109:55-61

XII. ATTACHMENTS

Optochin P discs QC Form

Policy Title	Optochin Disc	Policy #	MIC131043
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F:\Micro\QC\Reagent QC Forms\Optochin P discs QC Form

Policy Title	COVID-19	Policy #	MIC131069
Responsible	Laboratory Director	Revised/Reviewed	08/10/2020 10/18/2022

I. PURPOSE

ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs and nasal, nasopharyngeal or throat swabs eluted in viral transport media from individuals who are suspected of COVID-19 by their healthcare provider. Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW COVID-19 assay is also authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

II. PRINCIPLE

ID NOW COVID-19 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal, nasopharyngeal and throat swabs.

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 13, 2019. Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and in several Southeast Asian countries, Europe and more recently the United States. Cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

ID NOW COVID-19 is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument.

The reaction tubes in the Test Base contain the reagents required for amplification of SARS-CoV-2, as well as an internal control. The templates (similar to primers) designed to target SARS-CoV-2 RNA amplify a unique region of the RdRp segment. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, mixing and detection are provided by the instrument.

III. POLICY

Policy Title	COVID-19	Policy #	LAB131069
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The ID NOW COVID-19 test is a CLIA waived test. This policy and procedure is for Clinical Laboratory Scientists and MLTs who have successfully completed initial training and maintained annual competency.

IV. REAGENTS AND MATERIALS

1. Test Bases: Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.
2. Sample Receivers: Blue plastic components containing 2.5mL of elution buffer.
3. Transfer Cartridges: White plastic components used to transfer 2 x 100µL of sample extract from the Sample Receiver to the Test Base.
4. Swabs: Sterile swabs for use with the ID NOW COVID-19 Test
5. Positive Control Swab: The positive control swab ensures sample elution/lysis and workflow were performed correctly.
6. Negative Control Swab: The negative control swab ensures appropriate negative results are obtained.

V. STORAGE

Store kit at 2-30°C. The ID NOW COVID-19 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

VI. SPECIMEN COLLECTION AND HANDLING

Preferred specimen – Nasopharyngeal swab

Acceptable alternative specimens – Nasal swab and Throat swab

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

- Nasopharyngeal Swab samples

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Pass the swab directly backwards without tipping the swab head up or down. The nasal passage runs parallel to the floor, not parallel to the bridge of the nose. Using gentle rotation, insert the swab into the anterior nares parallel to the palate advancing the swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. DO NOT USE FORCE while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.

Use sterile foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal sample.

Policy Title	COVID-19	Policy #	LAB131069
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- Nasal Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, foam, HydraFlock Flocked swab (standard tip), HydraFlock Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

**** NOTE:** Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use in this assay.

- Throat Swab

Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.

For optimal performance, use the swab provided in the test kit. Alternatively, foam, or flocked flexible-shaft NP swabs can be used to collect nasopharyngeal samples.

**** NOTE:** Rayon swabs are not suitable for use in this assay.

Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, a direct nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection.

The use of transport media is no longer appropriate for this test system. Swabs received in VTM or any other transport media will be rejected for testing with the ID NOW instrument.

VII. QUALITY CONTROL

ID NOW COVID-19 has built-in procedural controls. The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting Review Memory on the instrument.

Procedural Controls:

ID NOW COVID-19 contains an internal control that has been designed to control for functionality of the amplification/detection process and reagents. In positive samples where target amplification is strong, the internal control is ignored and the target amplification serves as the 'control' to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust. At a low frequency, clinical samples can contain inhibitors that may generate invalid results.

Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

External Positive and Negative Controls:

Policy Title	COVID-19	Policy #	LAB131069
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Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW COVID-19 kits contain Positive and Negative Control Swabs. These swabs will monitor the entire assay. Test these swabs once with each time a new box is opened or a new shipment is received and once for each untrained operator.

Quality Control Swab Test Procedure

1. For QC testing, select Run QC Test on the Home screen, and follow the displayed instructions. Select COVID-19; select the test to be run.



2. Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.



Note: The QC test is run in the same manner as a patient test, refer to procedure beginning at step 4 "Loading the Components" for further instruction.

****Note: The ID NOW Instrument reports QC results as Pass or Fail.**

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

VIII. PROCEDURE

Before testing with ID NOW COVID-19, allow all samples to reach room temperature.

Step 1 - Select Test

- Touch screen to wake up instrument.
 - Enter UserID and Password



- Select Run Test; select COVID-19; select sample type (if prompted)

Policy Title	COVID-19	Policy #	LAB131069
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- Enter specimen accession number



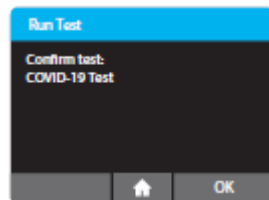
Step 2 - Orange Test Base

- Open the Lid and Insert Orange Test Base into Orange Test Base holder



CAUTION: Do not apply excessive force. Excessive force could damage the instrument.

Confirm that the correct test is displayed on the screen.



- Touch 'OK' to proceed.

CAUTION: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded. If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a self-test before proceeding to the Home screen. Press Run Test and restart the test using the correct Test Base.

Step 3 – Blue Sample Receiver

- Insert Blue Sample Receiver into the Blue Sample Receiver Holder

CAUTION: Do not apply excessive force. Excessive force could damage the instrument.

Policy Title	COVID-19	Policy #	LAB131069
---------------------	----------	-----------------	-----------



CAUTION: Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test. If the test is not started within 10 minutes, the instrument will time out and all test pieces (Test Base and Sample Receiver) must be removed and discarded. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.

- Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once Warm Up begins.



CAUTION: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.

DO NOT close the lid or insert the sample until prompted by the instrument.

Step 4 – Adding Specimen

Direct Nasal, Throat or Nasopharyngeal Swab:

- When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.



- Vigorously mix the swab in the liquid for 10 seconds. Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab.
- Once the swab is removed, touch 'OK' to proceed. Discard swab. (Skip to Step

CAUTION: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.

Policy Title	COVID-19	Policy #	LAB131069
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Step 5 - White Transfer Cartridge

- Press the White Transfer Cartridge into the Blue Sample Receiver. Listen for a click.

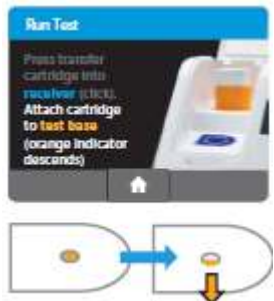
When the transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.



CAUTION: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.

- Lift and then connect the Transfer Cartridge to the Test Base.

When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.

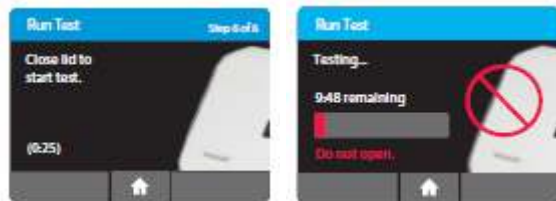


CAUTION: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false negative results.

Step 6 – Close lid

- Close the Lid when prompted. The lid must be closed with 30 seconds or the test will be aborted.

Policy Title	COVID-19	Policy #	LAB131069
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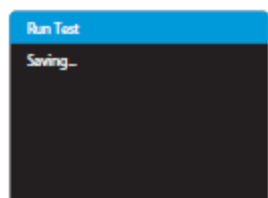


CAUTION: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument will proceed to the Home screen. Collect a new sample from the patient. Press Run Test and restart the test using a new Test Base and Sample Receiver.

CAUTION: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.

Step 7 – Testing Completed

- When amplification and detection is complete, the instrument will automatically print test results and save the data before advancing to the results screen. The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.



The Test Results screen displays either a Negative or Positive result for a successfully completed test. If a test error occurs, the display will read 'Invalid.' Refer to the Result Interpretation Section for Interpretation of Results.

- Press New Test to run another test, Press Home to return to the Home screen.

After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces. Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and clicking it into the Sample Receiver, by pressing into the Sample Receiver.



- Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Policy Title	COVID-19	Policy #	LAB131069
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- Place print out on Result Log.

If an Invalid result is received, one additional test may be run using the same Sample Receiver. The instructions below should be followed:

- Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. The connected Test Base and Transfer Cartridge **MUST** be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package may be used for this.
- Remove the blue Sample Receiver separately and carefully from the instrument. The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents.
- From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and **DO NOT** re-elute the swab.
- If repeat testing result is valid, report result. If repeat testing result is invalid, obtain new specimen.

IX. INTERPRETATION

When the test is complete, the results are clearly displayed on the instrument screen.

Instrument Display	Interpretation of Results and Follow-up Actions
	COVID-19 Positive
	COVID-19 Negative This result does not rule out co-infections with other pathogens.
	The presence or absence of COVID-19 Viral RNAs cannot be determined. Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

X. REPORTING RESULTS

Policy Title	COVID-19	Policy #	LAB131069
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Record result in LIS as RNA Detected or Not Detected under the test COVID-19.

The following text will print under the results automatically:

A Detected result is considered a positive test result for COVID-19. This indicates that RNA from SARS-CoVV-2 (formerly 2019-nCoV) was detected, and the patient is considered infected with the virus and presumed to be contagious. If requested by public health authorities, specimens will be sent for additional testing.

An Inconclusive result means not all of the testing targets were detected, additional sample collection may be considered. A Not Detected (negative) test result for this means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection.

A negative result does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions. If COVID-19 is still suspected, based on exposure history together with other clinical findings, re-testing should be considered in consultation with physicians. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

XI. LIMITATIONS and PRECAUTIONS

- The performance of the ID NOW COVID-19 was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen.
- As with any molecular test, if the virus mutates in the target region, COVID-19 may not be detected or may be detected less predictably.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.
- For use under an Emergency Use Authorization Only.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
- To be used in conjunction with the ID NOW Instrument.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test pieces sealed in their foil pouches until just before use.
- Do not tamper with test pieces prior to or after use.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots or from other ID NOW assays.
- Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.

Policy Title	COVID-19	Policy #	LAB131069
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- Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
- If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
- All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. Pieces must not be separated once they are assembled.
- All test pieces are single use items. Do not use with multiple specimens.
- Once reacted, the Test Base contains large amounts of amplified target (Amplicon). Do not disassemble the Test Base and Transfer Cartridge. In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW COVID-19 false positive test results.
- At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
- Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

XII. ATTACHMENTS

1. ID NOW Patient Result Log
2. ID NOW QC Log

XIII. REFERENCES

1. ALERE COVID-19 Package Insert, IN190000 Rev.1 2020/03

Policy Title	Commercially Prepared Media QC	Policy #	MIC131018
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

All commercially prepared media is tested for quality control by the manufacturers in accordance with NCCLS guidelines. It is the responsibility of this lab to maintain documentation verifying this QC and to verify that the media survived transportation without any deleterious effect for all non-exempt media as determined by CLSI (M22-A3). In most cases this will only necessitate a visual inspection and maintaining the documentation from the manufacturer. This documentation can be found on the Media QC Voucher from Hardy Media or on the removable package label for BBL media. Some types of media that have been shown to be less stable will require additional QC on receipt.

II. POLICY

Testing to be performed by Clinical Laboratory Scientists in the Microbiology Department.

III. REAGENTS

Media
QC Organisms
Loops

IV. STORAGE

Most media is stored 2-8°C until use. Media is good until expiration date listed on packages or stamped on media plates.

V. PROCEDURE

1. All media will be examined by the technician receiving each shipment visually for cracked petri dishes, unequal filling of plates, cracked plates, hemolysis, freezing, excessive bubbles and contamination.

All non-exempt media shipments satisfying these requirements will be signed off to that effect on the Media QC form. This documentation will be kept for at least 2 years.

2. In addition, the following media will be tested for specific performance: Campy, Chocolate, SPECTRA, MIO, MacConkey Sorbitol, Thayer Martin and V-agar. The microbiology Lab Tech will set aside one or two plates in the refrigerator and start the appropriate QC organisms. They will then fill out the corresponding Media QC Form including: date received, lot # and expiration date on the media QC log sheet and write "OK" for lots that pass a visual inspection according to the above mentioned parameters.
3. Once the QC organisms are ready, the microbiology CLS will inoculate the media and complete the "Set Up" column in the Media QC Form. Plates will be inoculated by using one or two well isolated colonies of the organism and streaking for isolation on the new lot of media. The CLS will read and record the results after the appropriate incubation period for media performance characteristics. See the table in the interpretation section for details on setting up each plate.

Policy Title	Commercially Prepared Media QC	Policy #	MIC131018
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4. Any QC that does not meet the expected results will be repeated using the Method of Inoculation for QC Corrective Action column in the table below. A Complete the Corrective Action Form will be completed and placed in the Media QC Log behind the corresponding tab. If QC is still out after repeat, start new organisms from cryobeads or Kwik Stik (if cryobeads unavailable).

NOTE: Brucella agar does not require QC to be performed prior to use, however, Brucella agar must be pre-reduced 18 – 24 hours prior to use.

VI. INTERPRETATION

Media	QC Organisms	ATCC	Expected Results	Incubation Temp	Incubation Environment
Campy	C. jejuni	33291	Growth	42°C	Campy bag
	E. coli	25922	Inihibited growth		
Chocolate	N. gonorrhoeae	43069	Growth	35°C	3-5% CO ₂
	H. influenzae	10211	Growth		
Spectra MRSA Agar	S. aureus	29213	No Growth	35°C	Aerobic
	S. aureus	43300	Blue colonies		
MacConkey Sorbitol	E. coli	25922	Pink	35°C	3-5% CO ₂
	E. coli (O157)	700728	Colorless		
MIO	E. coli	25922	+ / + / +	35°C	Aerobic
	K. pneumoniae	33495	- / - / -		
Thayer Martin	N. gonorrhoeae	43069	Growth	35°C	3-5% CO ₂
	S. epidermidis	12228	Inihibited growth		
V Agar	G. vaginalis	14018	Growth with diffuse beta hemolysis	35°C	3-5% CO ₂

VII. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.
2. The Hardy Media QC Manual Hardy Diagnostics Santa Maria, Ca.
3. QA for Commercially Prepared Microbiological Media, M22A NCCLS
4. TJC Interpretive Guidelines

Policy Title	Commercially Prepared Media QC	Policy #	MIC131018
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5. BBL Media Quality Control Manual Becton Dickinson, 2001

Policy Title	Accessioning Cytology Specimen Procedure	Policy #	PATH2282
Responsible	Laboratory Director	Revised/Reviewed	11/2020 10/18/2022

I. PURPOSE

To define the proper procedure for logging cytology specimens.

II. POLICY

All cytology specimen must be recorded in the appropriate specimen log.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Enter the patient's name, date of birth, medical record and billing number, along with the type of specimen it is in the APMG log.
2. Ensure that microbiology has aliquotted an appropriate amount of the specimen prior to the addition of fixative.
3. Fix the specimen by putting green cytology fixative in the container with a 50/50 ratio. If there are brushes with the specimen, smear them out on slides and spray fixative on them.
4. Take the paperwork and make one copy of each cytology requisition...for a total of 2 per specimen.
5. Also make one copy of each face sheet...for a total of two per specimen.
6. Make sure specimen is sealed tightly and put it in a biohazard bag. Put the original paperwork in the pocket on the side of the biohazard bag.
7. Place the bag with specimen and paperwork inside the APMG courier box.
8. Next take the extra requisition and the extra face sheet and punch holes in them, then put them in the three ring binder APMG courier log.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Autopsies	Policy #	PATH2349
Responsible	Laboratory Director	Revised/Reviewed	01/2024 12/15/2022

I. PURPOSE

To provide clear guidelines for the performance of autopsies for Coroner's cases or at the request of a physician.

II. POLICY

The policy of Watsonville Community Hospital is to follow the current California Healthcare Association (CHA) Consent Manual directions regarding autopsies and request permission for an autopsy as required by Medical Staff Rules & Regulations.

Autopsies that are not required by the Santa Cruz County's Coroner will be performed by Monterey County Medical Examiner at Monterey County Sheriff's Office per contract with Watsonville Community Hospital.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Establish if the death constitutes a coroner's case as indicated below. REPORTABLE DEATHS TO THE CORONER Government Code, State of California, Section 27491, directs the Coroner to inquire into and determine the circumstances, manner, and cause of the following deaths, which are immediately reportable.
 - A) Unattended deaths. (No physician in attendance or during the continued absence of the attending physician. Also, includes all deaths outside hospitals and nursing care facilities.)
 - B) Wherein the deceased has not be attended by a physician in the 20 days prior to the death.
 - C) Physician unable to state the cause of death. (Unwillingness does not apply. Includes all sudden, unexpected and unusual deaths and fetal deaths when the underlying cause is unknown.)
 - D) Known or suspected homicide.
 - E) Known or suspected suicide.
 - F) Involving any criminal action or suspicion of a criminal act. (Includes child and dependent adult negligence and abuse.)
 - G) Related to or following known or suspected self-induced or criminal abortion.
 - H) Associated with a known or alleged rape or crime against nature.
 - I) Following an accident or injury (primary or contributory). Deaths known or suspected as resulting (in whole or in part) from or related to accident or injury either old or recent.
 - J) Drowning, fire, hanging, gunshot, stabbing, cutting, starvation, exposure, alcoholism, drug addiction, strangulation or aspiration.
 - K) Accidental poisoning (food, chemical, drug, therapeutic agents).

Policy Title	Autopsies	Policy #	PATH2349
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- L) Occupational disease or occupational hazards.
- M) Known or suspected contagious disease and constituting a public hazard.
- N) All deaths in operating rooms and all deaths where a patient has not fully recovered from an anesthetic, whether in surgery.
- O) In prison or while under sentence. (Includes all in-custody and police involved deaths.)
- P) All deaths of unidentified persons.
- Q) All deaths of state hospital patients.
- R) Suspected Sudden Infant Death Syndrome (SIDS) deaths.
- S) All deaths where the patient is comatose throughout the period of the physician's attendance. (Includes patients admitted to hospitals unresponsive and expire without regaining consciousness.)

If in doubt, call the Coroner's office for assistance: A Coroner's Case can be released after the attending physician consults with the Coroner. The name of the Deputy Coroner releasing the body would be recorded in the chart by the physician or a nurse. The nurse or physician talking with the Coroner should request a written document to be mailed from the Coroner stating who released the body.

2. If the case is NOT a Coroner's case, and an autopsy is requested, follow the protocol below. As described in the CHA Consent Manual
 - A. Obtaining Autopsy
 - 1) The Medical Staff will be notified when a physician requested autopsy is performed.
 - 2) The Risk Manager must be notified of any physician or family requested autopsy.
 - 3) The Risk Manager must approve any autopsy that the hospital is financially responsible for.
 - 4) It is customary for the attending physician to discuss and request permission for the autopsy from the family if he/she desires one. The Monterey County Medical Examiner will perform autopsies only if requested by the attending physician. Nursing staff members should witness the signing of the autopsy consent form. The policy of this hospital is to use the CHA Consent Manual's directions concerning Authority for Autopsy (Attachment A – Form 11-1 Authorization for Autopsy).
 - 5) The priority in obtaining next-of-kin for autopsy permission should be as follows:
 - a. Spouse or registered domestic partner
 - b. A child of legal age
 - c. Parent
 - d. Sister or brother
 - e. Patient's aunt or uncle
 - f. Niece or nephew
 - g. Cousin
 - h. Second cousin
 - 6) If family requests a private autopsy, they will be instructed to contact a mortuary of their choice for arrangements.
 - 7) Coroner's cases preclude the need for signing permission by next-of-kin. However, the next-of-kin should be advised of the autopsy.
 - 8) When the next-of-kin are out of town, the permit can be obtained by phone with two witnesses (with a fax to follow).

Policy Title	Autopsies	Policy #	PATH2349
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B. Alerting Monterey County Coroner's Office

- 1) Inform the attending physician that a consultation with the pathologist is needed. An autopsy will not be performed until the attending physician discusses the case with the Coroner.
- 2) Inform the Coroner's Office of pending (or possible) autopsy, as soon as possible at (831) 755-3797
- 3) Send a copy of the patient's chart and signed autopsy permit or other documentation of permission to Monterey County Coroner's office with the body.
- 4) Notify the Coroner's office of any infections or radioactive hazard associated with the patient.

C. Handling of Body:

- 1) No autopsies will be performed at WCH due to the lack of a morgue facility with the materials to perform such.
- 2) Nursing Service will:
 - a. Deliver the body to the morgue and put in the refrigerator promptly. A manually operated lift is present in the morgue to assist in getting the body into the refrigerator. Deliver the chart to the Nursing Supervisor Office.
 - b. The patient's valuables should be put in the Security Office safe.
 - c. Inform the Coroner's Office that an autopsy has been requested and that transport of the body is needed.
 - d. The Coroner's Office will arrange the time/date when the autopsy can be performed.
- 3) Release of the Body Form - the Release of the Body Form is completed by the nurse in charge and kept with the chart. It should be noted if the body was infectious or radioactive.
- 4) Cleaning Morgue Room - Housekeeping will be responsible for seeing that the morgue room is cleaned.

V. REFERENCES

N/A

FORM 11-1

AUTHORIZATION FOR AUTOPSY

Patient Name: _____

Date: _____

Time: _____

1. I am one of the following persons authorized by law to direct disposition of the remains of the above-named patient.

☐ Father☐ Mother☐ Spouse☐ Brother/Sister☐ Registered domestic partner☐ Agent appointed in patient's power of attorney for health care☐ Child (over the age of 18)☐ Other: _____

2. I hereby authorize the performance of a post-mortem examination upon the above-named patient.
3. In the hope that the above-authorized examination may benefit others by protecting or preserving their lives and well-being, the undersigned also authorizes the examining physician and surgeon to remove such specimens, tissues, organs, organs, and to retain, preserve, conduct research, the same for such diagnostic, therapeutic, or other scientific purposes as he/she shall deem proper.
4. This authorization shall be subject to the following restrictions:
- _____
- _____
- _____

5. I understand that the examining physician and other physicians are not employees or agents of the hospital. They are independent medical practitioners.

Signature: _____

(patient/legal representative)

Print name: _____

(patient/legal representative)

Signature: _____

(witness #1)

Print name: _____

(witness #1)

Signature: _____

(witness #2)

Print name: _____

(witness #2)

Policy Title	Autopsies	Policy #	PATH2349
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Autopsy - Pathology Staff Quick Guide

Nursing floor will call Path requested autopsy

- ☐ Attending MD order is in chart
- ☐ Release of Remains form is in PBX
- ☐ Body is in morgue

NOTE: No autopsy will be performed for fetal demise of < 20 weeks gestation. The pathologist will inform the physician

Pathology Staff:

- ☐ Call 810-257-0212 (AMIS) for transport
- ☐ Call 831-755-3737 (Monterey Coroner Office) to arrange for autopsy (closed 12pm-1pm for lunch)
 - ☐ Fax "face sheet" to 831-755-3550
 - ☐ Send the following with body:
 - ☐ Autopsy Consent Form (MD's order)
 - ☐ Release of Remains
 - ☐ Any post operation discharge summaries from chart
- ☐ Send chart to Medical Records within 24 hours.

Monterey Coroner's office will call when autopsy is complete.

Pathology Staff

- ☐ Call 810-257-0212 (AMIS) for return transport back to mortuary or morgue.

Questions regarding report- call 831-755-3735

Policy Title	Pathology Specimens Policy	Policy #	PATH2438
Responsible	Laboratory Director	Revised/Reviewed	11/2020 10/18/2022

I. PURPOSE

The disposition of all specimens removed in the Operating Room must be defined.

II. POLICY

All specimens removed in the Operating Room must be submitted to the Pathologist. The specimens listed below can be disposed of or submitted to Pathology based on the surgeon's discretion.

III. DEFINITIONS

N/A

IV. PROCEDURE

The specimens listed below can be disposed of or submitted to Pathology based on the surgeon's discretion.

1. Cataracts.
2. Orthopedic hardware.
3. Rib portions (when removed for operative exposure).
4. Foreign bodies (for example, bullets) that for legal reasons are given directly, in the chain of custody, to law enforcement representatives.
5. Circumcision tissues from infants and babies less than two years of age.
6. Teeth, provided the number, including the fragments, are recorded in the medical record.
7. Ureteral stents.
8. Arthroscopy shavings.
9. Foreign bodies must be sent to Pathology if they are a result of a surgical mishap. Other foreign bodies can be disposed of at the discretion of the surgeon.
10. Hammer Toes and Bunionectomies tissue.
11. Scars.
12. Blood clot.
13. Unguis (Fingernails and toenails).

All specimens removed or obtained in other hospital departments (obstetrics, emergency room, special procedures, radiology, etc.) must be submitted to pathology. The physician may elect to submit to Pathology, or dispose of, the following listed specimens:

1. Grossly normal placentas obtained during routine vaginal deliveries with an obstetrician in attendance.
2. Foreign bodies (for example, bullets) that for legal reasons are given directly, in the chain of custody, to law enforcement representatives.
3. Foreign bodies that are not a result of a surgical mishap. These are disposed of in sharps containers or returned to the patient. Any foreign body removed as a result of a surgical mishap MUST be submitted to Pathology.

Policy Title	Pathology Specimens Policy	Policy #	PATH2438
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4. Avulsed nails removed in the Emergency Room.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
Responsible	VP, Ancillary Services	Revised/Reviewed	09/2020 10/31/2022

I. PURPOSE

This document outlines policies and procedures pertaining to testing on the i-STAT. In an effort to be concise, some information from the manufacturer's procedure manual may be excluded. It is recommended that this document be used in conjunction with the I-Stat System Manual Configuration and the i-Stat System Manual.

II. SCOPE

Level of Personnel: Emergency Department(ED) nurses and Clinical Laboratory Scientists who have completed the initial training and fulfilled the specific competency requirements.

Testing Site: Emergency Department and Clinical Laboratory

Approved Cartridges: i-STAT Troponin (cTnI) and CG4 for Lactate

III. POLICY

cTnI - Intended Use

The i-STAT cardiac troponin I (cTnI) test is an in vitro diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

CG4+ - Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the invitro quantification of lactate in arterial, venous, or capillary whole blood.

The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

Test Complexity

I-STAT troponin and lactate are classified as non-waived. Non-waived tests are less simple to perform and have additional skill, knowledge, and responsibility requirements. Different CLIA standards apply to non-waived tests.

Other venous whole blood samples, capillary and/or arterial samples tested using the cTnI and CG4 cartridges on the i-STAT 1 System are categorized by the FDA as moderate complexity.

Regulatory Requirement for Non-waived

1. General record keeping and document control system
2. Personnel assignment & competence assessment as required per type CLIA certificate
3. Proficiency testing: Participate in & treat required proficiency testing in the same manner as patient testing.
4. Individualized Quality Control Plan

Summary of the Procedure

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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To perform cartridge testing, the operator fills a cartridge with sample, seals the cartridge with its snap closure, and inserts the cartridge into the analyzer. Inserting the cartridge activates the analyzer. Alternatively, the cartridge test cycle can be initiated from the keypad/menu system. The unit-use cartridge contains all components to perform one or more tests including calibrating solution, sample handling system, sensors, and reagents. The analyzer automatically controls all steps in the testing cycle, which may include fluid movement, reagent mixing, calibration, and thermal control. Quality checks are performed continuously throughout the test cycle. Operator and patient IDs and patient chart information can be entered. When the test cycle is completed, results are displayed and the test record is stored.

IV. I-STAT Manufacturer's Quality System Instructions

1. Perform Daily Quality Control with Electronic Simulator

Check each Handheld reader with the Electronic Simulator, using either the internal or the external simulator, once on each day of use.

2. Check New or Replacement Handheld Readers with the Electronic Simulator

Use the Electronic Simulator, internal or external, to verify operation of a new or replacement handheld reader before use. The internal Electronic Simulator will automatically activate the first time a new or replacement handheld is used and after every 24 hours of use thereafter. The handheld can be customized to remind the operator to perform the simulator test (i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer) or automatically run the simulator (i-STAT 1 Analyzer) more frequently as required or desired.

3. Check Temperature Strip for a New Shipment of Cartridges

Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

4. Ensure Proper Cartridge Storage

- a. Ensure that refrigerator storage conditions for stored cartridges are between 2°C – 8°C (35°F –46°F).
- b. Ensure that cartridges are not exposed to temperatures exceeding 30°C (86°F).
- c. Ensure that cartridges are not used after the expiration date printed on the individual package and box.
- d. Ensure that cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box.
- e. Ensure that a cartridge is used immediately after it is removed from its package.
- f. Ensure that a cartridge taken from refrigerated storage is allowed to stand in its package at room temperature for 5 minutes before use, or that a box of cartridges stands at room temperature for one hour before use.

5. Ensure Thermal Probe Check is performed every 6 months on each handheld which could be done in conjunction with the software upgrade.

6. Train Staff on Avoidance of Pre- and Post-analytical Errors.

Train operators to avoid pre-analytical errors such as those associated to sample collection, delays in testing, inadequate sample mixing and post analytical errors such as result reporting and communication.

7. Update Software then Check with External Simulator

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Update the i-STAT System software as provided by Abbott Point of Care (APOC). Check the handheld with the external Electrical Simulator after software updates. The thermal probe reading can also be taken from this check.

8. Test Liquid Control for a New Shipment of Cartridges.

Check one cartridge from each newly received lot with the appropriate i-STAT control.

- **Tricontrols Level 1 and 3 Control**
- **Troponin 1,2 and 3 Controls**

9. Ensure Proper Cartridge Storage (Including Monthly Check).

- Verify that cartridges stored at room temperature are within expiration date and that cartridges have been out of the refrigerator less than the time frame indicated on the cartridge box.
- Use a liquid control to verify that the cartridges are performing properly, if the temperature at which the cartridges are stored is in doubt.
- Check storage conditions monthly by testing one cartridge from refrigerated storage with the appropriate i-STAT level control.

10. Review Interferences with Staff.

Review "Factors that Affect Results" listed in the Cartridge and Test Information sheets with clinical staff.

Cartridge and Test Information sheets are located on the Abbott Point of Care website (www.abbottpointofcare.com/Customer-Info-Center/Cartridge-and-Test-Info-Sheets.aspx).

V. Supplies and Storage Requirements

Cartridges	<p>Cartridges are sealed in individual pouches or portion packs.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Store the main supply of cartridges at a temperature between 2 and 8 °C (35 to 46 °F). <input type="checkbox"/> Do not allow cartridges to freeze. <input type="checkbox"/> Cartridges may be stored at room temperature (18 to 30 °C, or 64 to 86 °F) for the time frame indicated on the cartridge box. <input type="checkbox"/> Cartridges should not be returned to the refrigerator once they have been at room temperature, and they should not be exposed to temperatures above 30 °C (86 °F). <input type="checkbox"/> If the pouch has been punctured, the cartridge should not be used. <input type="checkbox"/> Write the date on the cartridge box or individual cartridge pouches to indicate the room temperature expiration date. <input type="checkbox"/> Cartridges should remain in pouches until the time of use. Do not use after the labeled expiration date.
Controls	<p>i-STAT cTnl Control Level 1 i-STAT cTnl Control Level 2 i-STAT cTnl Control Level 3</p> <p>i-STAT TriControls Level 1 i-STAT TriControls Level 3</p>

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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VI. Sample Collection

Sample Collection

Venipuncture – General

I.V. Line	Avoid drawing from an arm with an I.V. line. I.V. solutions will dilute the sample and may interfere with the tests.
Tourniquet	Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium and lactate due to a decrease in pH caused by localized production of lactic acid. If a tourniquet is applied for more than one minute while looking for a vein, release and reapply after two to three minutes.
Muscle Activity	Avoid extra muscle activity, such as clenching and unclenching the fist, which may increase potassium results.
Hemolysis	Avoid hemolysis (bursting of red cells) by allowing residual alcohol to dry over the puncture site and discarding a sample from a traumatic draw. For cTnI cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of cTnI. Collect blood collection tubes in the prescribed sequence to avoid interference due to carry-over of additive from one tube to the next:

Tube Order	<ul style="list-style-type: none"> • No additive • Citrate • Heparin • EDTA – Na2, K3 or K2 • Oxalate, fluoride, iodoacetate <p>If a citrate tube is drawn, draw a 5 mL plain discard tube before drawing the heparin tube</p>
Anticoagulants	<p>I-STAT cTnI cartridges require the use of either: heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or non-heparinized whole blood samples tested within <u>one</u> minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives. The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI readings.</p> <p>Cartridges for Troponin I/ cTnI: Venipuncture- lithium or sodium heparin collection tubes and disposable transfer device (e.g., 1 cc syringe and a 16 to 20 gauge needle). Alternately, a plain syringe or plain collection tube and disposable transfer device can be used if the sample is tested within one minute of patient draw.</p>
Fill Requirements	<p>Fill blood collection tubes with and without anticoagulant and syringes with anticoagulant. Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios.</p> <p>Gently mix blood (whether anticoagulated or not) immediately to avoid clotting.</p>
Mixing	<ul style="list-style-type: none"> • Invert a blood collection tube at least 10 times. • Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe.

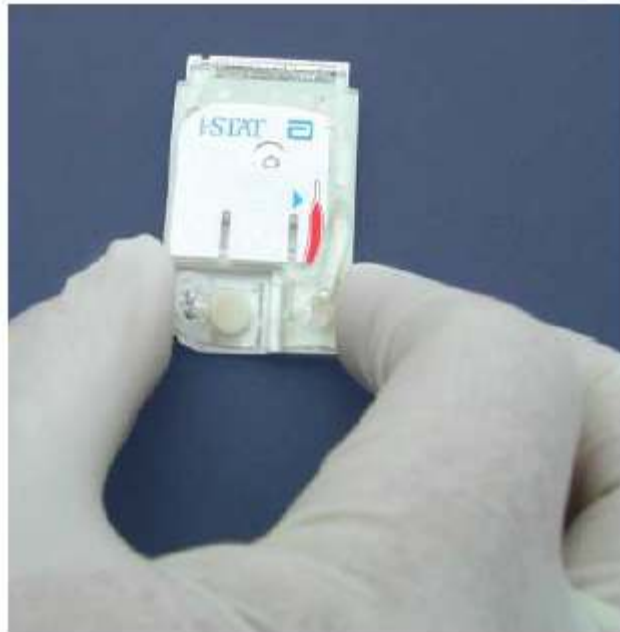
Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Exposure to Air	Test immediately if the sample is drawn into a blood collection tube. Expel any air bubbles immediately if the sample is drawn into a syringe or leave an air bubble next to the plunger and do not allow it to move through the sample.
Time to Test	For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. If testing is not immediate, remix blood collection tubes by gentle inversion at least 10 times. Roll syringes between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, and then discard the first two drops of blood. Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note It may be difficult to properly remix a sample in a 1.0 cc syringe.
Skin Punctures	Skin puncture samples are not recommended for cTnl and lactate cartridges.
Specimen Labeling	Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information: Patient name, sex, age Patient ID number
Criteria for Specimen Rejection	Time and date of collection Phlebotomist ID Doctor's name Evidence of clotting Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin

VII. Procedure for Handling Cartridges

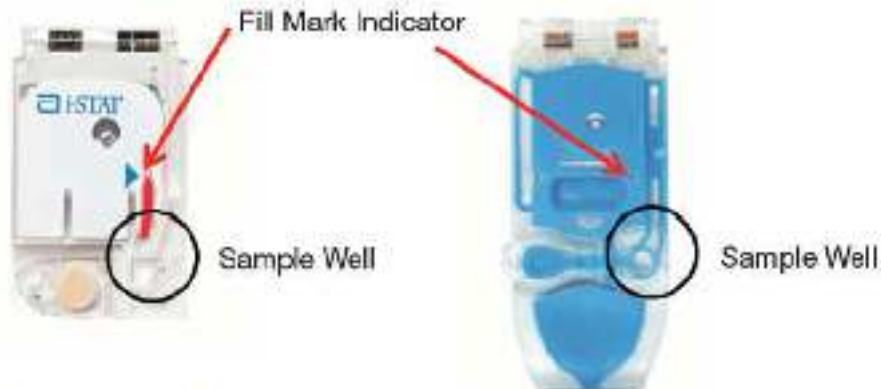
Preparation for Testing	
Select the Cartridge	Select the appropriate cartridge for the test or tests required. While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.
Room Temperature	Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage. A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). <ul style="list-style-type: none"> Allow a single cartridge to stand for <u>5 minutes</u> and a box of cartridges for <u>1 hour</u> at room temperature before use. Use a cartridge immediately after removing it from its protective pouch — prolonged exposure may cause a cartridge to fail a Quality Check. Once cartridges have been brought to room temperature, they should not be returned to the refrigerator. Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.
Contact Pads and Sensors	Avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge. Avoid touching the sensors on the top.
Calibrant Pack	Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.
Air Vent	Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.
Contamination	To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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VIII. Filling and Sealing Cartridge

1. Place the cartridge on a flat surface. Note the location of the sample well and fill mark indicator, as identified in the images below.



2. Mix the sample thoroughly.
 - a. Invert a blood collection tube at least 10 times.
 - b. Roll a syringe repeatedly between the palms for at least 5 seconds each in two different directions, and then invert the syringe repeatedly for at least 5 seconds. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe.
 - c. Expel a few drops of sample from the transfer device before filling the cartridge
3. Direct the tip of the transfer device (syringe, capillary tube, pipette, or dispensing tip)* into the sample well/inlet port, as shown below.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Note: Not directing the transfer device into the sample well could result in a sample not filling the cartridge or pooling on the sample well/inlet port.



4. Dispense a small amount of sample, ensuring it travels toward the fill mark before applying additional sample. Avoid creating a bubble on the sample well.

- Continue dispensing until the sample reaches the fill mark indicated on the cartridge.
- Ensure that there is sample in the inlet port, as well as the sample chamber

Properly Filled Cartridge

(cTnI, CK-MB, β -hCG and BNP)



These images display a properly filled cartridge. In the images at the top, the sample fills the sample chamber to the fill mark indicator.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
---------------------	---	-----------------	---------

Notice the images on the bottom show a full sample well, and no bubble appears in the sample pathway.



5.	<p>Fold the snap closure over the sample well:</p> <ol style="list-style-type: none"> Keeping your thumb or finger on the outside edge of the closure clasp, press the rounded end of the closure until it snaps into place. Ensure that the cartridge is completely closed before inserting it into the device. <p>To close the immunoassay cartridge with the plastic closure clip:</p> <ol style="list-style-type: none"> First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well.
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Properly Closed Cartridge



These images display properly filled and closed cartridges. As such, they may be inserted into the handheld.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Examples of Overfilled Cartridges



These images display overfilled cartridges. In the images at the top, the sample exceeds the fill mark indicator. In the images at the bottom, you will notice a bubble in the sample well.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

Examples of Under-filled Cartridges



These images display under-filled cartridges. In the images on the left, the sample well is insufficiently filled, and the sample does not reach the fill mark indicator.

In the images on the right, the sample well is sufficiently filled, but the sample does not reach the fill mark indicator.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

Examples of Improperly Closed Cartridges



These images display improperly closed cartridges. Although they were properly filled, they must be closed sufficiently before they may be inserted into the device.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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INSERTING AND REMOVING THE CARTRIDGE FROM THE ANALYZER

STEP	ACTION
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Inserting Cartridge into Analyzer

- | | |
|---|--|
| 1 | Align the cartridge with the contact pads facing up and toward the cartridge port. |
| 2 | Push the cartridge slowly and smoothly into the cartridge port until it clicks into place. |



Removing Cartridge from Analyzer

- | | |
|----|---|
| 3 | Do not attempt to remove the cartridge while the message "Cartridge Locked" remains on the screen. |
| 4 | When results are displayed, pull the cartridge straight out of the analyzer. |
| 5. | Dispose of the cartridge in a container for biohazards, following local, state, and national regulatory guidelines. |

IX. Procedure For Cartridge Testing with Troponin Controls

Procedures for testing cartridges with Troponin i-STAT controls

- A. i-STAT cTnI, BNP, and CK-MB Controls are ready-to-use liquid control requiring no reconstitution or frozen storage. They are stable until the expiration date on the vial label when stored unopened at 2–8 °C (35 to 46 °F). Once opened, the i-STAT cTnI Controls are stable for 30 days when stored tightly capped at 2–8 °C.
- B. Access the Control option under Quality Tests in the Administration Menu. Enter the required information. The handheld allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
- C. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
- D. Open the vial and transfer a drop of the solution into the i-STAT cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2–8 °C (35 to 46 °F).
- E. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
- F. Compare the result to the Value Assignment Sheet value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the handheld. Should results fall outside the range, refer to the Troubleshooting section of i-STAT 1 System Manual section 14 (Quality Control).
- G. If available, transmit results to the Data Manager.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Remedial Action:

If any results are outside the published expected ranges:

DO NOT USE cartridges from the suspect lot.

Quarantine the suspect lot.

Notify the i-STAT System Coordinator immediately.




Record the QC failure in the i-STAT QC Action Log along with the action taken.


X. Procedure for Cartridge Testing

Take the following cautions to prevent damage to the analyzer and to ensure the safety of the operator and the integrity of results.

- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.
 - Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.
 - Universal Precautions must be followed. To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See under "Cleaning the Analyzer and Downloader".
 - Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type, and other data that may affect the clinician's interpretation of results.
-
- **DO NOT insert cartridge to start test.**
 - **DO NOT open cartridge pouch before scanning the barcode.**
 - **If Quality Check Code 69 or 140 appears, see Analyzer Coded Messages Technical Bulletin for Troubleshooting Information.**

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
---------------------	---	-----------------	---------

1. Press  to turn on handheld.
2. Press  for i-STAT.
3. Follow the handheld prompts.
4. Scan the lot number on the cartridge pouch.
 - Position barcode 3-9 inches from scanner window on handheld.
 - Press and hold  to activate the scanner.
 - Align the red laser light so it covers the entire barcode.
 - The handheld will beep when it reads the barcode successfully.

Note: If cartridge pouch does not have a barcode, enter the lot number manually using the numbered keys or press  to bypass the prompt. You may ignore any letters in the lot number.

5. Continue normal procedures for preparing the sample, filling, and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.

The handheld must remain on a level surface with the display facing up during testing. A level surface includes running the handheld in the downloader/recharger.



7. Review results.

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

XI. Results

Calculations

The i-STAT handheld contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Suppressed Results

The i-STAT system will not display results is when these conditions occur:

- A. Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependent on the result of a test flagged as either > or <.

Action:

Send specimen(s) to the laboratory for analysis, if necessary.

- B. Flag appears for cartridge results, which are not reportable, based on internal QC rejection criteria.

Action:

Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.

- C. A Quality Check message will be reported instead of results if the handheld detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the handheld during the test cycle.

Action:

Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual: Troubleshooting section or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Reference Ranges:

ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE
		(arterial)	(venous)	
Lactate	mmol/L	0.36 – 1.25 Critical: 3.4	0.90 – 1.70	0.30 – 20.00
Troponin I/cTnI	ng/mL	0.00-0.04 Critical: >0.49		0.00-50.0

Support Services:

For technical assistance within the United States, please call Technical Services at 800-366-8020 toll free.

Reviewed By:	Signature: erg	Date: 7/2017
Reviewed By:	Signature:	Date:
Reviewed By:	Signature:	Date:

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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APPENDIX-A

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a “cause”^{1,2} an “action” message, and a code.

The Cause Message:

This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display “Sample Positioned Beyond Fill Mark”.

The Action Message:

This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction “Use Electronic Simulator” will be displayed. If the problem is related to an operator or cartridge, the instruction “Use Another Cartridge” will be displayed.

The Cause Code:

This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance. The codes are stored in the analyzer’s memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	Dead Batteries / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 Analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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2	Temperature Out of Range / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
4, 8	Analyzer Interrupted / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
11	Date Invalid / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	Invalid or Expired CLEW / See Manual	The CLEW standardization has expired. Download a valid CLEW. The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	Invalid or Expired CLEW / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	Analyzer Error / See Manual	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	Barcode Does Not Match Cartridge Type	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	Test Cancelled by Operator	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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20, 27-29, 32, 33, 40, 41, 45, 87	Cartridge Error / Use Another Cartridge	<p>These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.</p> <p>The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.</p>
42, 43	Cartridge Error / Use Another Cartridge	<p>These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.</p>

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
19	No Clot Detected / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 reappears, run the sample on an alternate methodology.
22, 25	Cartridge Error / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	Cartridge Error / Use Another Cartridge	<p>The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration.</p> <p>Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.</p>

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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26	Cartridge Error / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	Cartridge Error / Use Another Cartridge	<p>These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin.</p> <p>The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature.</p>
42, 43	Cartridge Error / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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Code Number	Cause/Action Message on Display	Explanation
79-81	Cartridge Error / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.
21	Cartridge Preburst / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	Unable to Position Sample / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35, 36	Sample Positioned Short of Fill Mark / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	Sample Positioned Beyond Fill Mark / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	Insufficient Sample / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	Cartridge Error / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	Cartridge Not Inserted Properly / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	Analyzer Error / See Manual	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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7. CLSI. H21-A3, Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline – Third Edition. CLSI document H21-A3 [ISBN 1-56238-363-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 1998.
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11. Shimizu H, Aono K, Masuta K, et al. Stability of brain natriuretic peptide (BNP) in human blood samples. Clin Chim Acta 1999;34:261-4.
12. Shimizu H, Aono K, Masuta K, et al. Degradation of human brain natriuretic peptide (BNP) by contact activation of blood coagulation system. Clin Chim Acta 2001;305:181-6.

13. Procedure Manual *for the i-STAT® System*

Policy Title	i-STAT Operations and Testing Procedure	Policy #	POC2118
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XI. REFERENCES

N/A

XII. STAKEHOLDERS

Policy Title	Point of Care Testing	Policy #	POC2583
Responsible	Laboratory Director	Revised/Reviewed	09/01/2020 10/31/2022

I. PURPOSE

To ensure the same quality of care and reliability of test results for all patients and clients of Watsonville Community Hospital, regardless of testing location and personnel performing testing.

II. POLICY

The Laboratory will coordinate and monitor all aspects of diagnostic testing performed outside of the laboratory by Watsonville Community Hospital employees or contract services.

III. DEFINITIONS

N/A

IV. PROCEDURE

Test systems will be evaluated for financial impact, accuracy and precision, complexity of testing (waived, moderate, or highly complex) and personnel requirements prior to purchase, trial, or use. Prior to a system obtaining the Laboratory Director's approval for use in patient testing, the Laboratory Director will ensure that:

1. The extent to which the results of POC tests are used in patient care (definitively or only as a screen).
2. The personnel responsible for performing and supervising POC testing are identified.
3. The personnel performing tests have adequate, specific training and orientation to perform the tests, and demonstrate satisfactory levels of competence.
4. The policies and procedures governing specific testing-related processes are current and readily available.
5. Quality control checks, as identified by the organization, are conducted on each procedure.
6. At a minimum, manufacturer's instructions are followed.
7. Appropriate quality control and test records are maintained.

Point of Care Testing Responsibilities

1. Operators
 - a. Understanding operation and policies pertaining to POC testing
 - b. Reporting problems and questions to the POCT Coordinator or Laboratory Director
2. Medical Director and Laboratory Director
 - a. Interfacing with Medical Staff to assess needs and concerns for present and future POC testing
 - b. Reviewing reports from POCT Coordinator and taking action as necessary to ensure compliance with policies and procedures
 - c. Participating in evaluation of new instruments and procedures
 - d. Reviewing policies and procedures pertaining to POC testing
3. Chief Nursing Officer

Policy Title	Point of Care Testing	Policy #	POC2583
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- a. Interfacing with Nursing Managers and Staff regarding POCT
 - b. Participating in planning and implementation of POCT
 - c. Reviewing policies and procedures pertaining to POCT
 - d. Taking action necessary to ensure Nursing compliance with POCT policies
- 4. Nursing Education Coordinator
 - a. Providing in-service training to Nursing staff
- 5. Point of Care Testing Coordinator
 - a. Interacting with regulatory agencies and surveyors to ensure compliance with current standards of care
 - b. Training, certification, and recertification of operators
 - c. QC review
 - d. Identifying problems and implementing solutions
 - e. Evaluating new instruments and test systems for possible use in future POC Testing
 - f. Providing reports as required

V. REFERENCES

- 1. Comprehensive Accreditation Manual for Laboratory and Point of Care Testing, Joint Commission for the Accreditation of Healthcare Organizations, Oakbrook Terrace IL, current edition.

VI. STAKEHOLDERS

N/A

Memo

1 March 2023

TO: Committees: P&T, MEC, Board
FROM: Jennifer Ura Gavin, Director of Pharmacy
SUBJECT: Policy #1569: Medication Administration Times

Meal times changed as a result of CHOW (Change of Ownership) survey, leading to slight discrepancy in medication timing for “before meal”.

New meal times: Breakfast: 0730
 Lunch: 1200 (no change)
 Dinner: 1730

Changes:

1. “AC” to 0700 (from 0730)
 - a. NOTEL reviewed time change with front line staff (to ensure no confusion with shift change on timing of medication)
2. Remove medication from Appendix 3
 - a. Pharmacy can time specific medication within frequency to ensure appropriate timing

APPENDIX 3: Specific Medications

Medication	Scheduled Time
Proton Pump Inhibitors (e.g., Pantoprazole)	0800
Chemotherapeutics (e.g., Epinephrine)	Daily 0800 0800-0900-1000-1100
Parenteral SSIs	0800 and 1700
Levothyroxine (Synthroid®)	0900
Short Acting Insulin (e.g., Regular, Lispro) Oral Hypoglycemics (e.g., Glipizide)	Daily - with breakfast BID - with breakfast and dinner
<u>Long Acting Insulin (e.g., NPH)</u>	Daily 0730 BID 0730 - 1800
Oral Antibiotics	Daily 0730 BID (Ceph) 0800 - 2100 TID (Amp) 0800 - 1100 - 1800 QID (Ceph) 0800 - 1100 - 1800 - 2100

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care		
Policy/Procedure #	1569	Effective	3/90	Page	1 of 9
Department Generating Policy	Pharmacy	Revised	3/20203/2023		

I. PURPOSE:

To provide guidelines for appropriate timing of medication for administration.

II. POLICY:

- A. The timing of medication administration, including how the medication is scheduled for intended administration and the actual time of administration shall be based on the nature of the medication and its clinical application.
- B. Scheduled dosing times shall be based on a predetermined set of “standard administration times” (e.g., 0900 for medications ordered once daily, 0900 and 2100 for medications ordered twice daily).
- C. Medications not eligible for scheduled dosing times shall require exact or precise timing of administration.
- D. Medications for which a one or two hour variance in the usual / scheduled dosing interval since the prior dose does not significantly change the medication’s therapeutic effect or otherwise cause harm shall be considered non-time critical scheduled medications.
- E. Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes (+/- 30 minutes) might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect.
- F. Exceptions to standardized medication times may be appropriate for improved patient care.

III. DEFINITIONS:

A. Scheduled medication:

1. Includes all maintenance doses administered according to a standard, repeated cycle of frequency (e.g., q4h, QID, TID, BID, daily, weekly, monthly, annually).
2. Does NOT include the following:
 - a. STAT and NOW doses
 - b. First doses and loading doses
 - c. One-time doses
 - d. Specifically timed doses (e.g., antibiotic for surgical patient to be given a specified amount of time before incision)
 - e. Time-sequenced medications (e.g., n-acetylcysteine, iodinated contrast media)
 - f. Drugs administered at specific times to ensure accurate peak/trough/serum drug levels
 - g. Investigational drugs in clinical trials
 - h. PRN medications

B. Time critical scheduled medication:

1. Early or delayed administration of maintenance doses of greater than 30 minutes before or after the scheduled dose may cause harm or result in substantial sub-optimal therapy or pharmacological effect.

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	2 of 9

C. Non-time critical scheduled medication:

1. Early or delayed administration within a specified range of either 1 or 2 hours should not cause harm or result in substantial sub-optimal therapy or pharmacological effect.

IV. PROCEDURE:

- A. When transcribing or entering new or recopied medication orders, the exact corresponding scheduled time is to be entered in the scheduled time as follows:

DAILY0900

BID0900 2100

TID0900 1500 2100

QID0900 1300 1700 2100

EVERY 2H.....even hours

EVERY 3H.....0000 0300 0600 0900 1200 1500 1800 2100

EVERY 4H.....0400 0800 1200 1600 2000 2400

EVERY 6H.....0600 1200 1800 2400

EVERY 8H.....0600 1400 2200

EVERY 12H...0900 2100

AC.....~~0730~~0700 1130 1630

PC0900 1300 1800

bedtime2100 – but may be given earlier or later according to patient’s actual sleep pattern

with meals.....0800 1200 1700

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	3 of 9

B. Medications NOT Eligible for Scheduled Dosing Times

1. The following medication orders (in inpatient and outpatient settings) are not eligible for scheduled dosing times, but rather follow the procedures listed.

Medication Order Type	Timing
One time “STAT” dose	Administer now, or as soon as possible. If patient’s clinical status demands, may override prior to review by pharmacist. If dose is delayed, contact prescriber.
One time or first dose “NOW”	Administer within 60 minutes. If patient’s clinical status demands, may override prior to review by pharmacist.
One time “ON-CALL”	These medications are given in the pre-procedure area just prior to a procedure (e.g., a surgical prophylaxis antibiotic should be given within 60 minutes prior to the incision).
One time “FOR PROCEDURE”	These medications are given during a procedure.
Administer “PRN”	Give as needed, according to timeframe ordered (e.g., q 4 hrs PRN heartburn).

C. Medications Eligible for Scheduled Dosing Times

Medication Order Type	Timing
Every 24 hrs, Every 12 hrs, Every 8 hrs, Every 4 hrs, etc.	These are scheduled according to the hospital’s “standard hourly administration time/first dose” grid. (See Section IV.A. of this policy) <ul style="list-style-type: none"> • The pharmacist will schedule the timing of the first dose, but the nurse may document “NOT ADMINISTERED” if the patient’s history reveals that the patient has already received a dose for that period (e.g., at home or in the ED)
Daily, BID, TID, QID	
BKF, LUN, SUP (breakfast, lunch, supper), w/MEALS, etc.	These are scheduled according to the anticipated meal time. <ul style="list-style-type: none"> • The nurse adjusts the actual administration time according to the actual meal time for the patient.

Guidelines for the administration and timing of new medications which are initiated between standardized dosing times are given in the hospital’s “standard administration time” grid. (See Appendix 1)

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	4 of 9

D. Target administration time window

1. The target administration time window for medications is as follows:

	Frequency	Window
Non-Time Critical	Medications scheduled for daily, every week or once monthly administration	+/- 2 hours from scheduled time
	Medications scheduled <u>more frequently</u> than daily, but <u>less than</u> every 4 hrs (e.g., every 12 hrs, every 8 hrs, every 6 hrs)	+/- 1 hour from scheduled time
Time Critical	Medications scheduled <u>every 4 hrs or more frequently</u> (e.g., every 4 hrs, every 2 hrs, every hour AND as noted in table below)	+/- 30 minutes from scheduled time

E. Additional time-critical scheduled medications:

1. Insulin dosing administration should adhere to the recommended dosing timeframe for each specific type of insulin.
 - a. Example: Rapid-acting lispro insulin should be administered at the time of the meal.
2. Time-critical drugs with 30 minute target administration times

Medication	Rationale for +/- 30 minutes target
<u>Scheduled</u> pain medications	Need to maintain adequate pain control
<u>Scheduled</u> transplant immunosuppressants	Need to maintain adequate serum concentrations to prevent organ rejection
Therapeutic doses of enoxaparin (LOVENOX)	Need to maintain adequate serum concentrations
Oral tetracyclines and oral quinolone antibiotics	These medications are timed apart from other medications (containing calcium, iron, magnesium, aluminum) that might interfere with absorption.
Valproic acid (Depakote), carbamazepine (Tegretol), Lithium, phenytoin (Dilantin)	These medications often have serum concentration levels scheduled to be drawn 12 hours post-dose.
Chronic, re-scheduled short-action opioids	To avoid break-through pain

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	5 of 9

F. Staff Education

1. Staff involved in medication administration will know when a scheduled medication is time-critical by education and ancillary comment.

G. Early or Late Administration of Medications

1. If a scheduled dose of a medication is late (e.g., patient off floor, dose not available, patient refusal, etc.), the dose is given as soon as possible.
 - a. How this process may impact the timing of the next dose is described in Appendix 2: “Guidance for How Late Doses Impact Subsequent Doses”.
2. Exceptions: The nurse notifies the physician or other practitioner responsible for the care of the patient prior to adjusting the timing of a medication dose in the following circumstances:
 - Chemotherapy
 - Insulin
 - Investigational drugs
3. In all other circumstances, the nurse is allowed to use their own judgment regarding the rescheduling of a late medication dose.
4. The nurse notifies the physician or other practitioner responsible for the care of the patient immediately if an early/late medication dose of medication:
 - Causes harm to the patient
 - Has a known potential for harm
 - Or if the outcome of the administration error is unknown (cannot be ascertained)
5. The nurse follows a similar process for administering medications early when circumstances require (e.g., patient is leaving floor).

H. Missing Dose of Medication

1. If a medication dose is administered so late as to fall onto the next scheduled medication time (+/- 2hrs), the dose is “missed”.
2. In the following circumstances, the nurse notifies the physician or other practitioner responsible for the care of the patient about the missed dose.
 - Chemotherapy
 - Antibiotics
 - Immunosuppressants
 - Anticoagulants
 - Narrow Therapeutic Index drugs (e.g., digoxin, phenytoin)
3. The nurse notifies the physician or other practitioner responsible for the care of the patient immediately if a missed dose of medication:
 - Causes harm to the patient
 - Has a known potential for harm
 - Or if the outcome of the administration error is unknown (cannot be ascertained)

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	6 of 9

I. Periodic Evaluation of Medication Administration Timing Policies

1. The facility will periodically evaluate these medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration.
2. Medication errors related to the timing of medication administration are tracked and analyzed to determine their causes.
3. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff determines whether there is a need to revise the policies and procedures governing medication administration timing.

REFERENCES

- Joint Commission Standard, 2012: MM.05.01.11 EP 3
- CMS letter dated November 18, 2011. Updated Guidance on Medication Administration, Hospital Appendix A of the State Operations Manual (SOM)
https://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter12_05.pdf
- CMS letter dated May 13, 2011. State Operations Manual (SOM) Hospital Appendix A Update.
https://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter11_28.pdf
- ISMP Acute Care Guidelines for Timely Administration of Scheduled Medication. 2011

Reviewed:	1st	2nd	3rd	4th	5th
Date:	<u>12/94</u>	<u>10/97</u>	<u>4/04</u>	<u>4/05</u>	12/07
By:	_____	_____	_____	_____	J. Gavin

Reviewed:	6th	7th	8th	9th	9th
Date:	10/09	_____	_____	_____	_____
By:	_____	_____	_____	_____	_____

Revised:	1st	2nd	3rd	4th	5th
Date:	8/12	6/15	2/19	3/2020	3/2023
By:	J.Gavin	J.Gavin	J.Gavin	J.Gavin	J.Gavin

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	7 of 9

APPENDIX 1: Standard Hourly Administration Times/First Dose Grid

- Medications ordered on an hourly basis (e.g., every 12 hrs) for inpatients will be scheduled according to the times listed below, unless specifically ordered otherwise by the physician or required by patient need.
- How the timing of a first dose impacts timing for the second dose is described in the chart.
- For certain medications (not first dose antibiotics, nor STAT or NOW medications), it may be appropriate to delay the first dose several hours to the next scheduled due time.

Every 24 hrs = 0900

0100 0200	0300 0400 0500 0600 0700 0800	0900	1000 1100 1200 1300 1400 1500 1600 1700 1800 1900 2000 2100 2200 2300 2400
→	Give first dose now & give 2 nd dose @ 0900 the next calendar day. If appropriate, may delay first dose till 0900 today	Give first dose now and 2 nd dose @ 0900 tomorrow	

Every 12 hrs = 0900 and 2100

0100 0200 0300 0400	0500 0600 0700 0800	0900	1000 1100 1200 1300 1400 1500 1600	1700 1800 1900 2000	2100	2200 2300 2400
Give first dose now and 2nd dose @ 0900	Give first dose now and 2nd dose @ 2100			Give first dose now and 2nd dose at 0900		

Every 8 hrs = 0600, 1400 and 2200

Every 6 hrs = 0600, 1400 and 2200																							
0100	0200	0300	0400	0500	0600	0700	0800	0900	1000	1100	1200	1300	1400	1500	1600	1700	1800	1900	2000	2100	2200	2300	2400
	Give first dose now and 2nd dose @1400								Give first dose now and 2nd dose at 2200								Give first now dose and 2nd dose at 0600						
→																							

Every 6 hrs = 0600, 1200, 1800 and 2400

0100 0200 0300	0400 0500	0600	0700 0800 0900	1000 1100	1200	1300 1400 1500	1600 1700	1800	1900 2000 2100	2200 2300	2400
Give first dose now and 2nd dose @ 0600	Give first dose now and 2nd dose @ 1200			Give first dose now and 2nd dose @ 1800			Give first dose now and 2nd dose @ 2400			Give first dose now and 2nd dose @ 0600	

Every 4 hrs = 0400, 0800, 1200, 1600, 2000 and 2400

0100 0200 0300	0400	0500	0600 0700	0800	0900	1000 1100	1200	1300	1400 1500	1600	1700	1800 1900	2000	2100	2200 2300	2400
→	Give first dose now and 2nd dose @ 0800		Give first dose now and 2nd dose @ 1200			Give first dose now and 2nd dose @ 1600			Give first dose now and 2nd dose @ 2000			Give first dose now and 2nd dose @ 2400			Give first dose now and 2nd dose @ 0400	

Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Provision of Care
Policy/Procedure #	1569	Page	8 of 9

APPENDIX 2: Guidance for How Late Doses Impact Subsequent Doses

A late dose should be administered as soon as possible.

- If administered SHORTLY after the dosing window, the timing of the next dose is not impacted.
 - Every 24 hr doses – within 8 hrs
 - Every 12 hr = 3 hrs
 - Every 8 hrs = 2 hrs
 - Every 4 hrs = 1 hr
- If administered farther outside the administration window, the timing of the next dose will be adjusted by the nurse by about 50% of the “late time”, and then the following dose will be given as scheduled.
 - “Late time” = “Actual administration time” – “scheduled administration time”
 - See examples below. Assistance from a pharmacist may be requested.
 - “Adjusted times” are not rescheduled in the MAR
- If a dose is administered so late that it occurs within the window of the next scheduled dose, a dose has been missed.

Examples

Once daily at 0900

0100 0200 0300 0400 0500 0600 0700 0800 **0900** 1000 1100 1200 1300 1400 1500 1600 1700 1800 1900 2000 2100 2200 2300 2400

If late dose given in this interval, delay next 0900 dose until ~1800 and then next dose is back on schedule at 0900	If prior late dose given in this interval, a dose has been “missed”	If late dose given in this interval, there is no impact on next dose	If late dose given in this interval, delay next 0900 dose until ~1300 and then next dose is back on schedule at 0900
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Twice daily at 0900 and 2100

0100 0200 0300 0400 0500 0600 0700 0800 **0900** 1000 1100 1200 1300 1400 1500 1600 1700 1800 1900 2000 **2100** 2200 2300 2400

If late dose given in this interval, delay 0900 dose until ~1300 and then next dose is back on schedule at 2100	If prior late dose given in this interval, a dose has been “missed”	If late dose given in this interval, no impact on next dose	If late dose given in this interval, delay 2100 dose until ~2400 and then next dose is back on schedule at 0900	If prior late dose given in this interval, a dose has been “missed”	If late dose given in this interval, no impact on next dose
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Every 8 hrs at 0600, 1400 and 2200

0100 0200 0300 0400 0500 **0600** 0700 0800 0900 1000 1100 1200 1300 **1400** 1500 1600 1700 1800 1900 2000 2100 **2200** 2300 2400

If late dose given in this interval, delay 0600 dose until ~0900 and then next dose is back on schedule at 1400	If prior late dose given in this interval, a dose has been “missed”	No impact on next dose	If late dose given in this interval, delay 1400 dose until ~1700 and then next dose is back on schedule at 2200	If prior late dose given in this interval, a dose has been “missed”	No impact on next dose	If late dose given in this interval, delay 2200 dose until ~0100 and then next dose is back on schedule at 0600	If prior late dose given in this interval, a dose has been “missed”	No impact on next dose
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Every 4 hrs = 0400, 0800, 1200, 1600, 2000 and 2400

0100 0200 0300 **0400** 0500 0600 0700 **0800** 0900 1000 1100 **1200** 1300 1400 1500 **1600** 1700 1800 1900 **2000** 2100 2200 2300 **2400**

No impact on next dose	Delay 0400 dose until ~0530 and then next dose at 0800	No impact on next dose	Delay 0800 dose until ~0930 and then next dose at 1200	No impact on next dose	Delay 1200 dose until ~1330 and then next dose at 1600	No impact on next dose	Delay 1600 dose until ~1730 and then next dose at 2000	No impact on next dose	Delay 2000 dose until ~2130 and then next dose at 2400	No impact on next dose	Delay 2400 dose until ~0130 and then next dose at 0400
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Policy/Procedure Title	Administration of Drugs: Medication Administration Times	Manual Location	Volume II – Assessment & Care of Patients		
Policy/Procedure #	1569	Effective		Page	9 of 9

APPENDIX 3: Specific Medication

Medication	Scheduled Time
Proton Pump Inhibitor (e.g., Protonix)	0600
Fluoroquinolones (e.g., Cipro, Levaquin)	Daily 0600 BID (Q12H) 0600 – 1600
Furosemide BID	0600 and 1800
Levothyroxine (Synthroid®)	0730
Short Acting Insulin (e.g., Regular, Lispro) Oral Hypoglycemic (e.g., Glipizide)	Daily – with breakfast BID – with breakfast and dinner
Long Acting Insulin (e.g, NPH)	Daily 0730 BID 0730 - 1630
Oral Antibiotics	Daily 0730 BID (Q12H) 0900 – 2100 TID (Q8H) 0600 – 1400 – 2200 QID (Q6H) 0600 – 1200 – 1800 - 2400
Epogen Alfa (Procrit®)	1200
Montelukast (Singular®)	1900
Oral H₂ Blocker (e.g. Pepcid)	2100 — if ordered > daily, give last dose at bedtime
Warfarin DAILY	2100
Anti-Lipids (“Statins”) daily	2200



To: P&T Committee
From: Jennifer Ura Gavin, Director of Pharmacy; Melanie Turowski and Kimberly Burgess, Clinical Dieticians
Date: 1 March 2023
Re: Policies #0129: Parenteral Nutrition Support Monitoring, #1413: Fat Emulsion Administration (Lipids) – Adult. #1430: Parenteral Nutrition Administration

Policy #0129: Parenteral Nutrition Support Monitoring:

- Changes to Triglyceride monitoring to be consistent with P#1413 below (baseline, then weekly)
- Weights daily (remove “minimum weekly weights”)
- Update references

Policy #1413: Fat Emulsion Administration (Lipids) – Adult.:

- Modify (increase) infusion duration to 24 hours to minimize complications resulting from lipid infusions (e.g., fat overload syndrome)
- Updates/changes to Triglyceride monitoring
 - E. Triglyceride initial and monitoring:
 1. A baseline triglyceride level should be taken prior to the initiation of parenteral nutrition.
 2. Triglyceride levels should be checked weekly while on parenteral nutrition.
 - a. Parenteral nutrition does not need to be stopped to check triglyceride level.
 - b. Goal for triglyceride level to be below 400 mg/dL.
 - c. Lipid infusion should be decreased if serum triglyceride level is between 400 to 500 mg/dL.
 - d. For serum triglyceride level > 500 mg/dL, a temporary discontinuation or reduction of infusion rate for 4 to 6 hours should be considered.
 - e. When the serum triglyceride level returns to < 400 mg/dL, lipid infusion can be restarted at a reduced rate.
- Update references (available)

Policy #1430: Parenteral Nutrition Administration:

- Changes to Triglyceride monitoring to be consistent with P#1413 below (baseline, then weekly)
- Weights daily (remove “minimum weekly weights”)
- Update references

Policy/Procedure Title	Parenteral Nutrition Support Monitoring	Manual Location	Provision of Care		
Policy/Procedure #	0129	Effective	7/94	Page	1 of 4
Department Generating Policy	Food Services, Pharmacy	Revised	5/20223/2023		

I. PURPOSE:

- A. To assure appropriateness and tolerance of Parenteral Nutrition
- B. To assist physicians in decisions regarding changes to Parenteral Nutrition support.

II. POLICY:

- A. The Nutrition Support Team (NST) is responsible for routine monitoring of all patients on Parenteral Nutrition (PN) utilizing the PN Protocol.
- B. Purpose of PN Protocol is to maintain adequate nutrition or improve under-nutrition when the gastrointestinal tract is not functional or adequate calories and nutrients cannot be provided via oral or enteral route.

III. PROCEDURE:

- A. Nutrition Support Team (NST)
 1. The NST consists of any of the following care team members:
 - Registered Dietitian (RD)
 - Clinical Pharmacist (RPh)
 - Registered Nurse (RN)
 - Physician (MD)
 2. RD and RPh will coordinate as needed.
 3. RN, and MD if available, will assist with evaluation of nutritional support.
 4. All patients on PN will be reviewed by the Dietitian within 24 hours of initiation, seven days a week.
 5. Utilizing the PN protocol, the NST will monitor patient's progress on PN.
 6. Physician will be contacted if immediate need for change exists by either RD or RPh, as appropriate.
 7. Any changes to PN orders will be documented by physician, or RN or RPh, using appropriate order entry method – e.g., CPOE (computerized physician order entry), written order, or telephone order.
 8. Documentation of progress and monitoring by the NST will be completed by the RD in the Nutrition Assessment Note located in the summary assessment section of the medical record in MedHost (HMS).
 9. Orders for PN shall be reviewed, ordered as appropriate, and approved daily.

B. PARENTERAL NUTRITION PROTOCOL

1. Indications:

- a. Non-functioning gastrointestinal tract
 - 1) Severe malabsorption not amenable to tube feeding, short bowel syndrome, intractable vomiting/diarrhea
 - 2) Bowel obstruction

Policy/Procedure Title	Parenteral Nutrition Support Monitoring	Manual Location	Provision of Care
Policy/Procedure #	0129	Page	2 of 4

- 3 Bowel rest
 - a. Severe pancreatitis, inflammatory bowel disease (IBD), high output enteric fistulas
 - c. Severe malnutrition or catabolism when patient is unable to be fed or fed adequately via enteral route (p.o./tube feeding) for ≥ 5 -7 days.
 - d. Surgical candidates with $\geq 10\%$ weight loss, multiple traumas, peritonitis, sepsis, burns
 - e. Critical care patients at high nutrition risk or severely malnourished and when enteral nutrition is not feasible.
 - f. In patients at low or high nutrition risk, use of supplemental parenteral nutrition may be considered after 7 to 10 days if unable to meet $> 60\%$ of energy and protein requirements by the enteral route alone.

2. **Contraindications:**

- a. Functioning gastrointestinal tract (i.e., functioning small intestine)
- b. Parenteral Nutrition anticipated for < 5 days
- c. Inability to obtain venous access
- d. Prognosis that does not warrant aggressive nutrition support (comfort care or hospice)

3. **Initiation Monitoring Guidelines:**

- a. Baseline biochemical data
 - 1) "TPN Baseline Panel" (TPN1) = CMP + Triglycerides + PO_4 + Mg
 - i. CMP (Comprehensive Metabolic Panel) = Na, K, Ca, Glucose, BUN, Cr, CO_2 , Cl, AST, ALT, Alkaline Phosphatase, Albumin, Total Protein
 - 2) Complete Blood Cell Count (CBC) with differential - includes platelets
 - 3) PT / INR (if placing a central line)
- b. Baseline weight, blood pressure, temperature
- c. Nutrition Assessment

4. **Maintenance Monitoring Guidelines:**

- a. All patients on Parenteral Nutrition (PN) will be monitored on a daily basis by the Nutrition Support Team. The following information as available (Table I) will be reviewed:
 - 1) "TPN Monitoring Panel" (TPN2) = Renal Panel + Mg
 - i. Renal Panel = Na, K, Ca, PO_4 , Glucose, BUN, Cr, Albumin,, CO_2 , Cl
 - ~~2) Triglyceride level at 1300~~
 - ~~3) 2) Weight (minimum weekly weights)~~
 - ~~4) 3) Accurate I&O = fluid balance~~
 - ~~5) 4) PO intake (if any)~~
 - ~~6) 5) Progress Notes~~
- b. Recommendations to change current regimen will be documented in the medical record by the Registered Dietitian ([RD](#)).
- c. Changes requiring immediate implementation will be phoned to the physician for discussion and/or modification to orders.
- d. Triglyceride (maintenance) level to be drawn ~~weekly with 1300 routine lab draw~~.
 - 1) Refer to policy# 1413: *Fat Emulsion Administration (Lipids) - [Adults](#)*.

Policy/Procedure Title	Parenteral Nutrition Support Monitoring	Manual Location	Provision of Care
Policy/Procedure #	0129	Page	3 of 4

5. Transitioning/Tapering Guidelines:

- a. Parenteral to enteral tube feeding
 - 1) Initiate tube-feeding ~~25-50ml/hr.~~
 - 2) Decrease TPN to half its total rate when patient tolerates enteral feeding and is meeting ½ to ¾ of caloric requirements.
 - 3) Increase tube feeding to desired nutritional requirements.
 - 4) Discontinue TPN after the last bag of solution infuses and enteral feedings are tolerated at the desired rate to meet nutritional requirements.
 - 5) PPN may be discontinued when patient tolerates enteral feeding and meets ½ to ¾ of caloric requirements.
 - i. PPN does not need to be tapered.
- b. Parenteral to Oral Feedings
 - 1) Begin with ~~clear~~ full liquid diet.
 - ~~2) Advance to full liquids as medically feasible / tolerated and initiate calorie count if needed.~~
 - ~~3)2) _____~~ Advance diet to solids as medically feasible / tolerated.
 - ~~4)3) _____~~ Decrease TPN to half its total rate when intake is 50% of solid PO (oral) diet.
 - ~~5)4) _____~~ Discontinue TPN when patient is consuming > 50% of PO diet.

REFERENCE:

- ~~1. Skipper, A, "Management of Total Parenteral Nutrition". Dietitian's Handbook of Enteral and Parenteral Nutrition. 2nd Ed. Aspen Publishers, Inc; 1998: 481-525.~~
- ~~2. Matarese, L & Gottschlich, M, "Contemporary Nutrition Support Practice, A Clinical Guide. 2nd Ed, Saunders; 2003: 227-241.~~
1. Charney, P. (2019). Initiation, Advancement, and Acute Complication. In *Pocket guide to parenteral nutrition* (pp. 109–110). essay, Academy of Nutrition and Dietetics.
2. Escott-Stump, S. (2022). Enteral and Parenteral Nutrition Therapy. In *Nutrition and diagnosis-related care* (pp. 937–938). essay, Academy of Nutrition and Dietetics.
3. American Society for Parenteral and Enteral Nutrition. National Advisory Group on Standards and Practice Guidelines for Parenteral Nutrition. Safe practices for parenteral nutrition formulations. ~~Jan. 1997.~~
4. Joint Commission Standard: MM.05.01.07 EP 2 - 4

Revised:	1st	2nd	3rd	4th	5th
Date:	1/01	1/04	12/03	12/07	4/10
By:	_____	_____	E MacKusick	E.MacKusick, J.Gavin, K.McNary	J.Gavin

Revised:	6th	7th	8th	9th	10th
Date:	5/2022	<u>3/2023</u>	_____	_____	_____
By:	NST	<u>NST</u>	_____	_____	_____

Reviewed:	1st	2nd	3rd	4th	5th
Date:	_____	_____	_____	_____	_____
By:	_____	_____	_____	_____	_____

Policy/Procedure Title	Parenteral Nutrition Support Monitoring	Manual Location	Provision of Care
Policy/Procedure #	0129	Page	4 of 4

TABLE I. Monitoring Guidelines for Parenteral Nutrition

VARIABLES	FREQUENCY OF MONITORING	
	FIRST WEEK	THEREAFTER
Energy Balance Weight	On admit	Weekly
Fluid Balance		
•Volume of infusate	Daily	Daily
•Oral intake if any	Daily	Daily
•Urinary output	Daily	Daily
•Other losses	Daily	Daily
Metabolic Variables		
•TPN Baseline Panel (TPN1) = CMP + Triglycerides + PO ₄ + Mg	Day 1	1 x per week
•TPN Monitoring Panel (TPN2) = Renal panel + Mg	Day 2, 3, 4	1-2 x per week
•Triglycerides	Day 2, 3, 4 w/1300 Lab draw Day 1	1-2 x per week w/1300 lab draw 1 x per week
•Glucose (fingerstick)	As ordered	As ordered
•CBC (includes platelets)	Day 1	1 x per week
•PT (INR)	Day 1	1 x per week
Urine Measurements		
• Urinalysis	As indicated	As indicated
• Urea nitrogen	As indicated	As Indicated
Physical Measurements		
• Temperature	Every shift	Every shift
• Blood Pressure	Every shift	Every shift

CMP (Comprehensive Metabolic Panel) = Na, K, Ca, Glucose, BUN, Cr, CO₂, Cl, AST, ALT, Alkaline Phosphatase, Albumin, Total Protein

Renal Panel = Na, K, Ca, PO₄, Glucose, BUN, Cr, Albumin, CO₂, Cl

Policy Title	<u>Parenteral Nutrition Administration</u>	Policy #	<u>PHARM1430</u>
Responsible	<u>Pharmacy Director, FANS</u>	Revised/Reviewed	<u>3/2023</u>

Policy/Procedure Title	<u>Parenteral Nutrition Administration</u>	Manual Location	<u>Provision of Care</u>		
Policy/Procedure #	<u>1430</u>	Effective	<u>5/07</u>	Page	<u>1 of 6</u>
Department Generating Policy	<u>Pharmacy, FANS</u>	Revised	<u>5/20223/2023</u>		

I. PURPOSE:

To provide guidelines for safe administration of Peripheral Parenteral Nutrition (PPN) and Total Parenteral Nutrition (TPN).

II. POLICY:

- A. Parenteral nutrition provides fluids, electrolytes, amino acids, multivitamins and trace elements to patients unable to receive adequate nutrition through the gastrointestinal route.
- B. Personnel shall observe parenteral nutrition precaution, as outlined in this policy.
- C. Please refer to the following policies for additional information:
 1. Policy #0129: *Parenteral Nutrition Support Monitoring*.
 2. Policy #1413: *Fat Emulsion Administration (Lipids) - Adults*

III. PROCEDURE:

- A. Responsibilities:
 1. Physicians: catheter placement, overall responsibility for nutritional content, and the duration of treatment
 2. Nursing Service: administration of solution and catheter care
 3. Pharmacy: preparation of solutions
 4. Dietary: review of nutritional status
 5. See policy #0129 for Nutritional Support Team collaboration
- B. Equipment
 1. Parenteral nutrition (PPN or TPN) solution
 2. Infusion pump tubing with 0.22 micron filter (from Central Distribution)
 4. Infusion pump
 5. Complete Parenteral Nutrition Physician Order Form (see attached form)
- C. Adult Parenteral Nutrition Orders:
 1. See attached "Adult Parenteral Nutrition (PN) Orders"
 - a. Orders may be written by physician
 - b. Order may be taken as a telephone order by Nurse or Pharmacist, and appropriately documented
 - c. If available, orders may be entered via CPOE (computerized physician order entry)

2. Clarifications:

a. IV fluids:

- 1) Previous orders for IV fluids shall be discontinued when PN starts, unless otherwise ordered or changed by physician.

b. IVPB medication:

- 1) Medications ordered IVPB that are added to PN will be discontinued once PN starts – eg, multivitamins, folic acid, thiamine, famotidine

Policy/Procedure Title	Parenteral Nutrition Administration	Manual Location	Provision of Care
Policy/Procedure #	1430	Page	-2 of 6

Policy Title	Parenteral Nutrition Administration	Policy #	PHARM1430
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D. Monitoring Guidelines (Nursing)

1. Base line weight, then ~~minimum weekly~~daily weight while on parenteral nutrition
2. Accurate I&O every shift.
 - a. Record parenteral nutrition separately.
3. Fingerstick blood glucose as ordered
4. Vital signs every shift (temperature, blood pressure)
5. Observe, record and report laboratory results per physician orders.
6. Refer to Policy #0129: *Parenteral Nutrition Support Monitoring*

E. Preparation and Distribution (Pharmacy):

1. Prepare all parenteral nutrition solutions in a primary engineering control device suitable for CSP's (compounded sterile preparations)
2. Adhere strictly to all infection control/aseptic technique policies and procedures.
3. Check order for incompatibilities and ensure that solutions, additives, and rates of administration are acceptable.
4. Check initial and final solutions for evidence of precipitation or microbial growth.
5. Compound the product.
6. Label the final product.
7. Ensure that a pharmacist checks the final product and the label prior to release from the Pharmacy.
8. Deliver the finished product to the patient care unit.

F. Administration (Nursing):

1. Patient must have central venous catheter inserted by physician for TPN therapy.
 - a. Peripheral line must be present for PPN therapy.
2. ~~FAX~~eCompleted Parenteral Nutrition Order Form to Pharmacy by 1300 for the solution to be available by the 1800 hang time.
 - a. Call Pharmacy regarding the status of orders ~~faxed-completed~~ after 1300.
3. Nursing will NOT add to parenteral nutrition solution.
 - a. Pharmacy staff will add all additives, including regular insulin, to the parenteral nutrition solution.
 - b. All additives will be included on the Pharmacy label affixed to the nutrition solution.
4. Parenteral nutrition is delivered to the patient care areas daily by Pharmacy staff on the 1700 round.
5. Prior to administration, visually inspect solution for cloudiness or precipitate.

6. Verify label for correctness against eMAR and physician order sheet / CPOE.
 - a. Ensure that the solution has not expired.
7. Set up solution, tubing and filter using aseptic technique.
 - a. Tape all non-Luer lock connections.
 - b. Distal port should be used to infuse TPN with a triple lumen catheter.
8. Administer solutions with an in-line 0.22 micron filter except lipid-containing solutions. A 1.2 micron filter should be used for all lipid-containing solutions.
9. Use an infusion pump to maintain the proper flow rate.
10. NEW STARTS: Initiate TPN at ½ of goal rate for 4 hours, then increase to goal rate.
11. Lines and filters are to be changed every 24 hours with each new bag of PPN or TPN.
12. All PPN and TPN solutions should be changed every 24 hours at 1800.

Policy Title	Parenteral Nutrition Administration	Policy #	PHARM1430
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13. Do not allow solution to run dry. Continue flow with D₁₀W, if necessary.

Policy/Procedure Title	Parenteral Nutrition Administration	Manual Location	Provision of Care
Policy/Procedure #	1430	Page	3 of 6

14. Do not draw or administer blood or add drugs through the catheter or Y-sites.

G. Discontinuing PN Therapy

1. Taper TPN therapy by administering ½ of current rate for 4 hours, then discontinue.
 - a. This taper schedule decreases the potential of rebound hypoglycemia that may occur if the TPN is abruptly discontinued.
2. PPN does not need to be tapered.
3. Hang the appropriate hydration or primary fluid at the ordered rate, or saline lock the central venous line, if ordered.

H. Changes in Formulation / Interruptions to Flow of PPN/TPN

1. All new orders and/or orders for changes in PPN or TPN formulation or rate must be received by the Pharmacy daily by 1300 in order to be mixed and available for the standard 1800 hang time.
2. Pharmacist will coordinate with Nursing staff regarding the status of all orders received after 1300.
 - a. Physician will be updated with status of “after 1300” order by either pharmacist or RN.
3. For PPN/TPN orders received after 1300, an IV of D₁₀W may be initiated until PPN/TPN is available.
4. If a PPN or TPN order is changed, the present bag will be infused until 1800.
5. All changes to rate and formulation will be effective with the new bag which will be available at 1800.
 - a. Physician has the option of tapering or discontinuing the bag or hanging D₁₀W until the new bag is prepared by Pharmacy and available at the standard 1800 hang time.

I. Administration of IV Antibiotics:

1. If possible, use a separate line to infuse antibiotics.
2. Call Pharmacy for questions regarding compatibility.
3. Hang all compatible antibiotics into an injection port below filter.
4. Suggested procedure if a peripheral line is not possible and antibiotics are not compatible with TPN:

- a. Hang a bag of D₁₀W.
- b. Turn off TPN solution while antibiotic is infusing.
- c. Attach the tubing from the D₁₀W bag at the injection site below the infusion pump and filter.
- d. Piggyback the antibiotic into the D₁₀W using appropriate secondary tubing.
- e. Run the D₁₀W while the antibiotic is infusing.
- f. NOTE: This procedure applies to TPN running through a central venous line only.
 - 1) Procedure does not apply to Peripheral Parenteral Nutrition (PPN).
 - 2) PPN may be interrupted to administer any IV antibiotic.

J. Complications:

1. Precipitate formation

- a. Caused by improper addition of medication into solution or line, or improper manufacturing of the solution.
- b. Action:
 - 1) Stop the TPN solution immediately.
 - 2) Start replacement with D₁₀W and new tubing.
 - 3) Notify physician.

Policy/Procedure Title	Parenteral Nutrition Administration	Manual Location	Provision of Care
Policy/Procedure #	1430	Page	4 of 6

Policy Title	Parenteral Nutrition Administration	Policy #	PHARM1430
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- 4) Notify Pharmacy (pharmacist) immediately.
 - 5) Monitor patient's vital signs, respiratory status.
2. Infection
- a. Signs and Symptoms
 - 1) Glucosuria
 - 2) Hyperglycemia
 - 3) Redness, drainage, pus at catheter site
 - 4) Sudden temperature spike
 - 5) Lethargy, restlessness
 - b. Prevention
 - 1) Strict adherence to aseptic technique during catheter manipulation.
 - 2) Use of dedicated TPN port on multi-lumen catheters (generally the distal port should be the dedicated port).
 - 3) Change tubing every 24 hours per protocol.
 - 4) Change dressing every 96 hours per protocol or PRN as needed.
 - c. Action to be taken after infection determined:
 - 1) Notify physician,
 - 2) Anticipate the following:
 - i. Discontinuing TPN
 - ii. Hanging D₁₀W
 - iii. Discontinuing catheter
 - iv. Obtaining cultures of catheter tip and/or blood cultures. ([Refer to Infection Control policy: #2297](#))

3. Osmotic Diuresis

a. Signs and Symptoms

- 1) Large urine output
- 2) Glucosuria
- 3) Hypotension
- 4) Poor skin turgor
- 5) Decreased level of consciousness

b. Prevention

- 1) Use infusion pump at all times
- 2) Monitor fingersticks and blood glucose as ordered
- 3) Observe, record, and report accurate intake and output

c. Action

- 1) Notify physician
- 2) Assess vital signs.
- 3) Anticipate the following:
 - i. Fluid volume replacement
 - ii. Blood glucose check
 - iii. Insulin administration

4. Electrolyte Imbalance

a. Signs and Symptoms:

- 1) Refer to a nursing or medical text for specific imbalances (most common – potassium, calcium, magnesium) or Policy #0129: *Parenteral Nutrition Support Monitoring*

Policy/Procedure Title	Parenteral Nutrition Administration	Manual Location	Provision of Care
Policy/Procedure #	1430	Page	5 of 6

<u>Policy Title</u>	<u>Parenteral Nutrition Administration</u>	<u>Policy #</u>	<u>PHARM1430</u>
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b. Action:

- 1) Observe, record and report lab values.
- 2) Notify physician of abnormal “Critical” values.

REFERENCE:

1. ~~Skipper, A, "Management of Total Parenteral Nutrition". *Dietitian's Handbook of Enteral and Parenteral Nutrition*. 2nd Ed. Aspen Publishers, Inc; 1998: 481-525.~~
2. ~~Matarese, L & Gottschlich, M, "Contemporary Nutrition Support Practice, A Clinical Guide. 2nd Ed, Saunders; 2003: 227-241.~~
1. Charney, P. (2019). Initiation, Advancement, and Acute Complication. In *Pocket guide to parenteral nutrition* (pp. 109-110). essay, Academy of Nutrition and Dietetics.
2. Escott-Stump, S. (2022). Enteral and Parenteral Nutrition Therapy. In *Nutrition and diagnosis-related care* (pp. 937-938). essay, Academy of Nutrition and Dietetics.
3. American Society for Parenteral and Enteral Nutrition. National Advisory Group on Standards and Practice Guidelines for Parenteral Nutrition. Safe practices for parenteral nutrition formulations. ~~Jan. 1997.~~
4. Joint Commission Standard: MM.05.01.07 EP 2 – 4

Reviewed:	1st	2nd	3rd	4th	5th
Date:	1-01	5-04	12-07	_____	_____
By:	Nursing/ Dietitian	Nursing/ Dietitian	MacKusick, McNary, Gavin	_____	_____
Revised:	1st	2nd	3rd	4th	5th
Date:	4/10	5/2022	_____	_____	_____
By:	J.Gavin	Dietary/Pharmacy	_____	_____	_____

+ **Adult Parenteral Nutrition (PN) Orders** +

Diagnosis: _____ Allergies: _____

- PN orders or changes must be received by Pharmacy by 1300 daily.
- Hang new bag daily at 6 PM. Discard previous day's bag.

1 FORMULATION - Please check box for desired formulation.

<input type="checkbox"/> Central Line 5/20 w/lytes Protein 5 % (50 grams/L) Dextrose 20 (680 kcal/L)	<input type="checkbox"/> Peripheral Line 4.25/5 Protein 4.25% (42.5 grams/L) Dextrose 5% (170 kcal/L)
--	--

Central 5/20

Peripheral 4.25/5

2	INFUSION RATE - Please indicate desired rate. Lipids will infuse separately. Please see #4 below
----------	---

- Infuse at ½ the ordered rate for 4 hours when initiating and discontinuing TPN therapy.
- Dextrose 10% may be hung if therapy is interrupted > 15 minutes, or until PN available.
- Discontinue IV fluids once PN starts, unless otherwise ordered by physician.
- Medications previously ordered IVPB will be discontinued once included in PN solution.

3	ELECTROLYTES & ADDITIVES - Indicate desired electrolytes if different from Standard.
----------	---

<input type="checkbox"/> Standard Electrolytes	<input type="checkbox"/> Changes to Standard Electrolytes	Additives:
Sodium 35 mEq/L Potassium 30 mEq/L Magnesium 5 mEq/L Calcium 4.5 mEq/L Phosphate 15 mM/L Acetate 80 mEq/L* Chloride 39 mEq/L	Sodium _____ mEq/L Potassium _____ mEq/L Magnesium _____ mEq/L Calcium _____ mEq/L Phosphate _____ mM/L Acetate _____ mEq/L Chloride _____ mEq/L	<u>Standard:</u> (Added unless otherwise noted or crossed out) Multivitamins Daily Trace Elements Daily <u>Optional:</u> Regular Insulin _____ Units/day Famotidine _____ mg/day Other: _____
* (Acetate in PPN: 70 mEq/L)		

4	LIPIDS 20% (2kcal/mL) - Infuse over <u>12-24</u> hours. Administer from 6 PM to 6 AM.
----------	---

☐ 250 mL (500 kcal) daily ☒ 250 mL every other day ☐ 250 mL twice weekly (Tues & Fri)
(250 kcal per day average) (142 kcal per day average)

5	OTHER ORDERS:
----------	----------------------

DIETICIAN:	Nutrition assessment; Nursing to notify
NURSING:	Daily: Body weight, I&O
LABS:	TPN baseline panel, CBC, PT – Day 1, then weekly
	TPN monitoring panel – Day 2,3,4, then weekly
	Triglyceride – Day 2,3,4, then weekly w/1300 labs
	1, then weekly

Place Patient ID Label Here

Policy/Procedure Title	Fat Emulsion Administration (Lipids) - Adult	Manual Location	Provision of Care		
Policy/Procedure #	1413	Effective	5-04	Page	1 of 2
Department Generating Policy	Pharmacy, FANS	Revised	12/2020 3/2023		

I. PURPOSE:

To provide guidelines for safe administration of lipids (fat emulsion).

II. POLICY:

Fat emulsions will be infused per hospital policy.

III. PROCEDURE:

A Order:

1. Check physician's order or Parenteral Nutrition Order Form.
2. Check patient allergies to determine if allergic to eggs.
 - a. If allergic, notify physician and do NOT administer fat emulsion (lipids).

B. Equipment:

1. Fat Emulsion
2. Non-DEHP tubing – available from Central Distribution
 - a. Example:” Nitroglycerin tubing”

C. Who Can Perform: IV Certified RNs

1. Wash hands.
2. Explain procedure to patient.
 - a. Confirm patient is NOT allergic to eggs.
3. Inspect fat emulsion for opacity and consistency of color and texture.
 - a. If separation or discoloration present, return to Pharmacy and obtain new emulsion.
4. Swab secondary port on the primary line with alcohol.
5. Attach primed needle-free access pin to tubing and insert into port below the filter.
6. Administration [start](#) time ~~is~~ [shall be](#) 1800.
7. Infuse over [12-24](#) hours (~~ie, from 1800 to 0600 next day~~)
8. Observe patient during infusion for signs of immediate allergy or fat intolerance:
 - a. Chills, fever, flushing, diaphoresis, dyspnea, chest or back pain, headache, nausea, dizziness.
9. Monitor patient for delayed lipid intolerance:
 - a. Elevated liver function tests, elevated serum lipids.
10. Lipids may be infused through a central or peripheral line.

D. Documentation

1. Document any side effects/complications and actions taken in the narrative of Nursing Notes
 - a. Complete ADR if appropriate
2. Record total volume of lipids (generally 250ml of 20% concentration):
 - a. I&O Record

Policy Title	Fat Emulsion Administration (Lipids) Adults	Manual Location	Provision of Care
Policy #	1413	Page	2 of 2

b. eMAR

~~E. Triglyceride (maintenance) level to be drawn with 1300 routine lab draw:~~

- ~~1. "Intravenous lipids may be restricted to a dose providing essential fatty acids (10 of total energy as lipid) only if the fasting serum triglyceride exceeds 400 to 500 mg/dL prior to starting TPN; they should be avoided altogether if the fasting level exceeds 1000 to 2000 mg/dL." (References: 1 & 2)~~
- ~~2. "Upper limits for triglyceride are not well established in the literature. For pediatrics, levels have been suggested at 250 mg/dL during continuous lipid infusion; for adults 300 to 350 mg/dL 6 hours post infusion has been suggested." (Reference 1) "It is recommended that triglyceride levels of less than 400 mg/dl should be maintained while lipids are being infused". (Reference 2)~~

E. Triglyceride initial and monitoring:

1. A baseline triglyceride level should be taken prior to the initiation of parenteral nutrition.
2. Triglyceride levels should be checked weekly while on parenteral nutrition.
 - a. Parenteral nutrition does not need to be stopped to check triglyceride level.
 - b. Goal for triglyceride level to be below 400 mg/dL.
 - c. Lipid infusion should be decreased if serum triglyceride level is between 400 to 500 mg/dL.
 - d. For serum triglyceride level > 500 mg/dL, a temporary discontinuation or reduction of infusion rate for 4 to 6 hours should be considered.
 - e. When the serum triglyceride level returns to < 400 mg/dL, lipid infusion can be restarted at a reduced rate.

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10.7. Joint Commission Standard: MM.05.01.07 EP 2-4

Reviewed:	1 st	2 nd	3 rd	4 th	5 th
Date:	12/07	5/2022	_____	_____	_____
By:	Mackusick, McNary, Gavin	NST	_____	_____	_____
Revised:	1 st	2 nd	3 rd	4 th	5 th
Date:	12/2020	3/2023	_____	_____	_____
By:	P.Serra, J.Gavin	NST	_____	_____	_____

Policy Title	Electronic Documentation in Rehab Services	Policy #	REHAB2784
Responsible	Director of Rehab	Revised/Reviewed	<u>02/04/2024</u> <u>01/24/2023</u>

I. PURPOSE

To provide a procedure for accurate, standardized documentation through the HMS electronic medical record system for inpatients in Rehab Services.

II. POLICY

All clinical staff in rehab services will be trained and will complete appropriate competencies in electronic documentation of patient care services and will consistently document all inpatient services provided through the system as available. All hospital approved confidentiality regulations will apply to access of and documentation in the system. Two patient identifiers will be used to ensure documentation on the correct patient.

III. DEFINITIONS

NA

IV. PROCEDURE

Licensed Physical, Occupational and Speech Therapists will be trained and complete competencies in the Clinical View area of the electronic documentation system in order to gather appropriate information to evaluate the patient, and in the Patient Care area to document evaluation and treatment provided. Physical Therapist Assistants will be trained and complete competencies in the Patient Care areas only in order to document treatment provided, per licensure. Rehab Aides will be trained if appropriate in the Clinical View area in order to verify orders and assist in providing information on the patient status to the therapists.

1. Physical Therapists will complete as indicated one or more of the following documents under the Assessments section of Patient Care:
 - a. Rehab-Physical Therapy IP Initial Evaluation
 - b. Rehab-Physical Therapy IP Treatment Note
2. Occupational Therapists will complete as indicated one or more of the following documents under the Assessments section of Patient Care:
 - a. Rehab-Occupational Therapy IP Initial Evaluation
 - b. Rehab-Occupational Therapy IP Treatment Note
3. Speech Language pathologists will complete as indicated one or more of the following documents under the Assessments section of Patient Care:
 - a. Rehab-Speech Therapy Clinical Dysphagia Evaluation
 - b. Rehab-Speech Therapy IP Initial Evaluation
 - c. Rehab-Speech Therapy IP Treatment Note
 - d. Rehab-Videofluoroscopic Swallow Study
4. Physical Therapist Assistants will complete as indicated the following documents under the Assessments section of Patient Care:
 - a. Rehab-Physical Therapy IP Treatment Note

Policy Title	Electronic Documentation in Rehab Services	Policy #	REHAB2784
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Documentation will be signed electronically and saved as part of the electronic medical record. If the patient is treated more than once a day, a separate treatment note will be completed for each encounter. Documentation of services and time spent in treatment will be consistent with charges entered into the patient's account.

V. REFERENCES

NA

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Speech Therapists, Physical Therapy Assistants, Rehab Tech

Policy Title	Pain Assessment	Policy #	REHAB1933
Responsible	Director of Rehabilitation Services	Revised/Reviewed	<u>02/26/2024</u> <u>01/24/2023</u>

I. PURPOSE

To provide effective pain monitoring and pain management for patients to enhance healing and promote physical and perceived wellness.

II. POLICY

A complete pain assessment is the cornerstone of all effective pain management. It is the responsibility of all rehabilitation department licensed clinical staff to assess and periodically reassess the patient's pain and/or relief of pain. Patients have a right to appropriate assessment and management of pain. Pain assessment, intervention, reassessment, education, and documentation will occur in a consistent, accurate and timely manner.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Pain assessment is documented during the initial evaluation of all patients using the appropriate, hospital approved pain scale based on the patient's developmental needs (visual and numeric).
 - a. Intensity / level of pain, using a pain intensity rating scale. The rating scale is individualized according to age, cognitive ability and/or language skills by utilizing one of the following four methods:
 - i. Number Scale from 0 (no pain) to 10 (worst possible pain).
 - ii. Words describing pain, which corresponds to the 0-10 number scale.
 - iii. Faces describing the degree of pain for pediatric / cognitively impaired or non-communicative persons, which also corresponds to the 0-10 scale.
 - iv. Behaviors and physical manifestations for infants and non-verbal children. These also correspond to the 0-10 number scale.
 - b. Quality of pain, e.g. character, frequency, location, sharp, ache, burn, throb, dull, etc.
 - c. Location of pain. Ask the patient to point to the site or sites of pain – also can use the attached form at initial assessment.
 - d. Present pain management system and effectiveness / pain relief measures. This includes the patient's medication history, past interventions, and effectiveness.
 - e. Alleviating and aggravating factors. Assess for factors that increase or aggravate the pain.
 - f. The patient's pain goal. Record the patient's acceptable pain goal, utilizing the 0-10 number scale or other pain rating scale used to assess the degree of pain.
2. Ongoing Assessment
 - a. Evaluate and address all pain complaints with pain control mechanisms. Pain control mechanisms to be included in the plan of care may include, but are not limited to the following:
 - i. modality intervention (i.e. heat, ice, ultrasound, electrical stimulation, iontophoresis, TENS);
 - ii. soft tissue work / massage.
 - iii. appropriate therapeutic exercises for pain relief.
 - iv. stress management education.
 - v. relaxation techniques education.

Policy Title	Pain Assessment	Policy #	REHAB1933
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- vi. recommendations of appropriate positioning/body mechanics to alleviate/reduce pain.
- vii. other information as appropriate.
- b. Any education provided regarding pain management is documented in the patient's daily progress notes, as well as on the multidisciplinary education form (if appropriate at the facility/hospital).
- c. Reassessment of pain is documented in the patient's daily progress notes. Outpatients should have a before treatment and after treatment assessment each treatment day.

V. REFERENCES

N/A

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Speech Therapists, Physical Therapy Assistants

Policy Title	Ultrasound	Policy #	REHAB1930
Responsible	Director of Rehab	Revised/Reviewed	<u>02/04/2024</u> <u>12/13/2022</u>

I. PURPOSE

Therapeutic Ultrasound is a modality used in Physical and Occupational Therapy:

- A. To increase cell permeability and healing.
- B. To decrease nerve conduction velocity.
- C. To alter connective tissue for the reabsorption of calcium.

II. POLICY

Ultrasound is used for patients with diagnoses including but not limited to bursitis, capsulitis, osteoarthritis, low back strain, muscle spasms, neuromas, phantom limb sensations, scar tissue, Herpes Zoster, neuralgia, contusions, ligamentous strains.

Ultrasound may be used for wound care. Ultrasound promotes tissue healing by local tissue heating which increases blood flow, increases cell membrane permeability and diffusion of metabolites due to stable cavitation, can stimulate the release of histamine from mast cells, stimulates fibroblasts to secrete more collagen and stimulates release of wound factors that stimulate fibroblast proliferation.

Ultrasound may be used for ischemic skin ulcers including stage III and IV pressure ulcers and undetermined wounds.

Do not use ultrasound over the epiphysis of growing bone, over reproductive organs, over the heart, eye, or pregnant uterus, over the spinal column or cephalic region, areas of impaired circulation or sensation, metal ions (topical treatments must be flushed out with saline) tissue previously treated with radiation or x-ray, deep vein thrombosis, or in cases of acute infections or malignant lesions. Use caution with vascular abnormalities.

III. DEFINITIONS

NA

IV. PROCEDURE

Prepare the patient for the application of ultrasound and explain ultrasound. Prior to the first treatment, inquire as to the presence of metallic objects in the body. Check age and diagnosis for possible contraindications. Expose area to be treated, evaluate, and inspect the area.

1. Apply a thin coat of a coupling agent (aquasonic gel) to the area to be treated. Spread gel with sound head. Turn timer to desired exposure time and dosage to level needed.
2. Inform the patient that they should feel little, if any, sensation from the treatment. Apply treatment head to the area to be treated. Do not artificially heat the sound head.
3. Set the machine to the desired level of output and observe indicator to see that the output is constant. Recheck the setting periodically. Output is determined by the condition and area to be treated.
4. The sound head should be kept moving at all times with firm and complete contact with the patient's skin. Do not allow head to stop its motion during application.
5. Treatment time is usually approximately eight (8) minutes per area.

Policy Title	Ultrasound	Policy #	REHAB1930
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6. Make sure that the unit is off before removing the sound head from the patient's skin so as not to destroy the crystal in the soundhead. Do not run machine in air.
7. Recommended treatment for superficial lesions is 3 MHz for more superficial absorption and for deeper lesions 1 MHz.
8. Documentation should include, but not limited to:
 - a. Treatment parameters (machine settings).
 - b. Area treated and description of area.
 - c. Response to treatment.
9. For treatment of uneven surfaces of the body, ultrasound can be used in a water bath, with water used as the coupling medium. The body part should be kept submerged throughout the treatment time and the treatment head kept moving parallel to the surface of the skin as much as possible.

V. REFERENCES

NA

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Rehab Tech

Policy Title	Hot Packs	Policy #	REHAB2066
Responsible	Director of Rehabilitation Services	Revised/Reviewed	<u>12/13/2022</u> 02/25/2024

I. PURPOSE

To provide established guidelines for the safe and most effective application of this modality.

Indications include, but are not limited to:

1. Arthritic pain, myofascial pain and restrictions, muscle pain and spasm.
2. To prepare soft-tissue or joint for myofascial release or joint mobilization.

Contraindications:

1. Neuropathy/area of decreased sensation.
2. Open wound.
3. Decreased mental status.
4. Third trimester of pregnancy.

II. POLICY

A standard set of principles and guidelines will be followed in the application of hot packs.

III. DEFINITIONS

Hot Pack: Absorbent material heated in hot water, wrapped around the body or a portion of the body, and covered with dry material to hold in the moist heat.

IV. PROCEDURE

1. Preparations

- i. Determine the location (body part) for heat application.
- ii. Check the unit.
 - a. The unit should be grounded.
 - b. The water should be hot - between 150 degrees to 170 degrees.
 - c. The water should cover the packs at all times. If water needs to be added, add it at the end of the day.
 - d. Use deionized water.
- iii. Check the packs.
 - a. The proper size packs should be ready to use.
 - b. The packs should be thoroughly soaked.
 - c. The packs should be hot.
- iv. Have all necessary materials ready to use. Tongs will be needed for removing small packs from the unit.

2. Starting the Treatment

- i. Explain the procedure to the patient.
 - a. The heat from the packs should be comfortably warm, not hot, and explain why.
 - b. It may take several minutes for the patient to feel the warmth.
 - c. Patient will be provided with a mechanism to let staff know if the packs are too hot or too heavy, or if any other discomfort develops.

Policy Title	Hot Packs	Policy #	REHAB2066
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- d. Patient should not move as this may cause the packs to become unwrapped and may cause burns.
 - ii. Use caution - the packs are hot and heavy, and the patient can be easily burned.
 - iii. Check the skin for any unusual marks before the treatment is started.
 - iv. Check the skin sensation. Use hot packs with extreme caution if sensation is lacking or diminished.
 - v. No part of the unpadded pack should touch the patient. For hygienic purposes, several thicknesses of toweling should be used on the area to be treated.
 - vi. Check the patient after a few minutes.
 - a. More toweling may be needed between the pack and the patient no matter which technique is used.
 - b. Do not remove toweling or change the pack as they begin to cool
 - vii. The treatment time is usually 10 to 20 minutes.
 - viii. Apply one layer of toweling to the exposed side of the pack in order to reduce loss of heat and moisture.
3. Terminating the Treatment
- i. Take the pack off the patient and remove the toweling.
 - ii. Replace the pack in unit and close the unit lid.
 - iii. Dry patient thoroughly.
 - iv. Check skin carefully for any unusual redness.
 - v. Dispose of the towel that was in contact with the patient's skin or clothing in the linen hamper.
4. Additional Points of Consideration
- i. Do not allow packs to dry out as they will become hard and brittle. If the packs are used only occasionally, unplug the unit but leave the packs in the water.
 - ii. New packs should be soaked overnight.
 - iii. When activating new units or a unit which has not been used for some time, allow the water and packs to heat overnight before use.

V. REFERENCES

N/A

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Rehab Techs

Policy Title	Electrical Stimulation	Policy #	REHAB1927
Responsible	Director of Rehabilitation Services	Revised/Reviewed	02/25/2021 12/13/2022

I. PURPOSE

To provide established guidelines for the safe and effective use of this modality.

1. To assess and treat nerve and muscle tissues.
2. To enhance local circulation, tissue healing, and reduce edema.
3. To reduce muscle spasms and decrease pain.
4. To increase range of motion.
5. To manage neuromuscular conditions.
6. To provide muscle reeducation and facilitation.
7. To maintain muscle integrity.

II. POLICY

Contraindications/Precautions

1. Electrical stimulation should not be used over abnormal skin surface, scar tissue, presence of a cancerous malignancy, hemorrhagic diathesis and tuberculosis, cardiac pacemaker, or other implantable electrical device or near recent or nonunion fracture site. Do not use this modality on a female patient during pregnancy. Do not electrically stimulate over, through, or near the heart, or over the carotid sinus.
2. Before beginning therapy, ensure the intensity controls are set to zero to avoid an accidental surge in current.
3. Do not place the electrodes closer than 1cm to each other to avoid blistering or burning.
4. Refer to literature that accompanies the Electrical Stimulation device for additional protocols and summaries involving use.

III. DEFINITIONS

Electrical stimulation (e-stim) is the use of a device to send gentle electrical pulses through the skin. Two common devices are: Electrical muscle stimulation (EMS) to help repair muscles. Transcutaneous electrical nerve stimulation (TENS) to help with pain.

IV. PROCEDURE

1. Patient should be in a comfortable position.
2. Make sure the skin in the area to be treated is free from oils, creams or perspiration which can increase resistance to the current.
3. Select the correct type of current for the patient's symptoms and signs.
4. With electrodes in place, increase voltage slowly to obtain the desired sensation or contraction of the muscle. Check skin often during treatment. Treatment should last 10-20 minutes.
5. Heat or ice pack treatment may be used in conjunction with electrical stimulation.
6. Terminating the treatment: Turn the intensity control(s) to zero and the power off. Remove

Policy Title	Electrical Stimulation	Policy #	REHAB1927
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the electrodes and check the skin for any irritation.

7. Documentation should include, but not limited to:
 - a. Document treatment parameters including type of current used.
 - b. Area of the body treated.
 - c. Duration of treatment.
 - d. Response to treatment if applicable.

V. REFERENCES

N/A

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants

Policy Title	Crutch Training/Fit	Policy #	REHAB1926
Responsible	Director of Rehabilitation Services	Revised/Reviewed	02/25/2021 12/13/2022

I. PURPOSE

1. To assure correct crutch fit according to the patient's height and arm length.
2. To maximize functional gait effectiveness/efficiency when ambulating with crutches.

II. POLICY

- Crutch training/fit should not be performed on patients who exhibit one or more of the following:
1. Decreased weight bearing status on both lower extremities.
 2. Insufficient upper extremity strength.
 3. Insufficient balance for safe ambulation.
 4. Inability to correctly observe limited weight bearing status.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Crutches must be properly fitted. Length of crutch should be two fingers width below armpit. Position of handgrip should be 25 – 30 degrees angle at elbow. Adjust the handle height so that patient has approximately 25 degrees of elbow flexion when standing erect with crutches in place for gait.
2. Instruct the patient in appropriate crutch gait pattern for diagnosis and weight bearing status. Include stair climbing, curbs and ramps if applicable. Instruction may also include, but not limited to:
 - a. Reason crutches are ordered, i.e. mild balance problem, lower extremity involvement.
 - b. Types of crutches: Auxiliary type and forearm type.
 - c. Fitting of crutches: Two fingers width below armpit.
 - d. Position of handgrip: 25 - 30 ° angle at elbow.
 - e. Walking patterns:
 - i. Two-point pattern: Left crutch/right foot, right crutch/left foot.
 - ii. Three-point pattern: Crutches are moved with the effected leg.
 - iii. Four-point pattern: Right crutch/left leg then left crutch/right leg, not done simultaneously as with two-point pattern.
 - iv. Swing-to pattern: Body weight is lifted and swings forward, feet are placed in line with the crutches.
 - v. Swing-Through pattern: Similar to swing-to except that feet are placed ahead of the crutches.
 - f. Precautions:
 - i. Never rest body weight on the top of the crutches. Excessive pressure exerted in the armpits can cause nerve damage. Push with hands for leverage.

Policy Title	Crutch Training/Fit	Policy #	REHAB1926
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- ii. Swing-to and swing-through patterns require that the patient momentarily lose and regain balance, so patient must be guarded carefully.
 - iii. Do not pivot when turning. Take small steps or hops.
 - iv. Keep both crutches in one hand when preparing to stand or sit allowing the free hand to hold the surface where the patient is coming from or going to.
- g. How to stand and sit safely:
 - i. Chair should be well supported.
 - ii. Crutches out from under arms when sitting.
 - iii. Hands on arm of chair or seat of chair for support.
 - iv. Rest extremity on floor for increased stability.
- h. How to master stairs and curbs:
 - i. To go up a curb or stairs face the stairs/curb. Put the crutches close to the first step or curb.
 - ii. Push onto the crutches and put uninjured leg on the first step.
 - iii. Put weight on uninjured leg that is on the first step. Bring both crutches and the injured leg onto the step at the same time.
 - iv. If holding onto a railing with one arm, put both crutches under the other arm. Use the railing to help go upstairs.
 - v. To go down a curb or stairs, stand with the toes of uninjured leg close to the edge of the step.
 - vi. Bend the knee of uninjured leg, slowly lowering both crutches along with the injured leg onto the next step.
 - vii. Lean on crutches. Slowly lower the uninjured leg onto the same step.
- i. How to put weight on leg or foot:
 - i. Full weight bearing - allowed to put full body weight on the affected side.
 - ii. Partial weight bearing - Allowed to put approximately 50% of body weight on the affected side.
 - iii. Toe-touch weight bearing - Allowed to put toe down onto floor when walking in order to provide stability during gait. Allowed only to put the smallest amount of weight on the affected side.
 - iv. Non-weight bearing - No weight on the affected side. Hold affected side in front of, or in back of the body.

V. REFERENCES

NA

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants

Policy Title	Care of Patients with IV's	Policy #	REHAB1924
Responsible	Director of Rehabilitation Services	Revised/Reviewed	02/24/2021 12/13/2022

I. PURPOSE

To establish guidelines for care of patients with IV(s) that provide venous route for administration of fluids, medications, blood or nutrients.

II. POLICY

Patient care activities will be performed without disruption of IV assembly.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Assess IV site for infection around insertion site assuring it is clean and dry, with no pain, redness or swelling. Report to nurse any problems identified.
2. Limit excessive motion at the IV site.
3. Do not utilize heat at the IV site unless specifically ordered to do so.
4. Ensure that the IV fluids are elevated above the IV catheter site and the heart level.
5. If problems are observed with the IV line, i.e. blood is observed in the line, do not attempt to clear it but call the nurse instead.
6. If the IV has a piggy-back in place, be careful not to separate the lines and avoid contamination by touching the junction.

V. REFERENCES

NA

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Speech Therapists

Policy Title	Arthroscopy and Arthrotomy	Policy #	REHAB2062
Responsible	Director of Rehab	Revised/Reviewed	02/04/2021 12/13/2022

I. PURPOSE

To provide quality patient care through the achievement of the following goals for the patient:

- A. Maximized strength, ROM, and decreased pain.
- B. Safe/functional ambulation with or without assistive devices.
- C. Effective, individualized home exercise program with clear, written instructions and family training if applicable.

II. POLICY

Physical Therapy will have available for physician utilization a typical protocol for knee arthrotomy/arthroscopy patients.

III. DEFINITIONS

NA

IV. PROCEDURE

PROGRAM

- A. Initial evaluation will include mention of:
 1. History of the problem.
 2. Objective signs (strength, range of motion, weight-bearing status, gait pattern).
 3. Plan of treatment including goals.
- B. Immediate post arthroscopic (or outpatient, if applicable) treatments will include:
 1. Gait Training on level and stairs if appropriate with appropriate assistive device and weight bearing status instructed as per physician order.
 2. Therapeutic exercise as ordered to increase ROM and strength to decrease pain. Exercise may include, but not be limited to:
 - a. Range of motion, passive static stretch and active assistive
 - b. Strengthening: active assistive/resistive and isometric
 - c. Stationary bicycle/treadmill (endurance training, cardiovascular)
 - d. Functional Electrical Stimulation (FES)
 3. Pain Relief
 - a. Modalities
 - b. Myofascial release
 - c. Joint protection (knee support if applicable)
- C. Daily treatments will include:
 1. Exercise as indicated for improving range of motion and strength. (FES may be indicated, if quad strength is poor to fair.)
 2. Instruction in gait and functional activity with crutches or walker as needed.
 3. Pain and Edema control.
 4. Discharge Planning when post-discharge follow-up is indicated.
- D. Discharge Visits
 1. Document quality of quadriceps contraction, range of motion, functional level.
 2. Document patient knowledge of home exercise, utilizing demonstration - return demonstration.
 3. Appropriate adaptive equipment will be recommended for home use.

Policy Title	Arthroscopy and Arthrotomy	Policy #	REHAB2062
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V. REFERENCES

Journal of Orthopedic Sports Physical Therapy, JOSPT.org, February 28, 2021

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Speech Therapists

Policy Title	Iontophoresis Monitoring	Policy #	REHAB1931
Responsible	Director of Rehabilitation	Revised/Reviewed	2/23/2023

I. PURPOSE

To provide guidelines for administering Iontophoresis as a part of a patient's treatment plan.

II. POLICY

Iontophoresis involves the application of a low voltage continuous constant current to push a charged drug into the skin or other tissue. Iontophoresis has been found beneficial in treating overuse injuries. The central process of iontophoresis is the movement of ions. The basis of ion transfer lies in the principle that like poles repel and unlike poles attract. The ions of the medications used in iontophoresis are then repelled into the skin by the identical charge of the electrode placed over it. If the therapist feels that iontophoresis is an appropriate modality intervention for the patient, a prescription specifically stating to include iontophoresis must be obtained prior to initiating treatment.

III. DEFINITIONS

Iontophoresis: a technique of introducing ionic medicinal compounds into the body through the skin by applying a local electric current.

IV. PROCEDURE

1. Obtain prescription for administration of iontophoresis. If the plan of care specifically states iontophoresis, and the physician has approved the plan of care, this is also acceptable as a prescription. The prescription or plan of care should specify:
 - a. Name of medication: Dexamethasone
 - b. Medication strength: 4mg/ml
 - c. Amount of medication per dose: 1ml or 2ml depending on size of electrodes used
 - d. Frequency and duration of treatment, e.g. 3 X a week for 2 weeks. In this way, the correct amount of medication for the patient's course of therapy can be prescribed.
2. Medications used in the administration of iontophoresis are obtained through the facility pharmacy. Once the treatment plan has been signed and approved by the Physician, scan or fax the treatment plan to Pharmacy where the Pharmacist will dispense the appropriate amount of the required medication labeled for the individual patient.
3. All medications used in the application of iontophoresis are to be kept in a locked cabinet. Medication used is to be documented in the patient's chart. All medication is to be drawn immediately prior to use into a syringe.
4. Electrodes are obtained through the hospital purchasing department.
5. For the first treatment, explain the procedure to the patient, including the benefits and risks of the modality. Ask the patient if they have any adverse reactions/allergies to medications, specifically, those used in iontophoresis.
 - a. Advise the patient that the direct current used in iontophoresis can cause some mottled erythema under either electrode which generally resolves within a few hours.
 - b. The patient should be advised to report any burning or pain or other reactions during the treatment at once.

Policy Title	Iontophoresis Monitoring	Policy #	REHAB1931
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- c. The patient should avoid unnecessary movement during treatment to ensure that inadvertent disconnection of an electrode or lead wire does not occur.
6. Inspect the area of the skin to be treated, looking for abrasions, lacerations, scar tissue or inflammation.
7. Clean the area to be treated.
8. Prepare the delivery electrode by attaching the appropriate lead wire and filling the electrode drug reservoir with the appropriate amount of medication. Place it over the treatment site.
9. Prepare the ground electrode with the grounding wire. Place this electrode approximately 4 inches away from the delivery electrode. This electrode may also be placed on the opposite side of the joint if deemed appropriate by the therapist.
10. Turn the iontophoresis unit on according to manufacturer specifications and directions. If wireless electrodes are being used (IontoPatch), inform the patient to leave the pads in place at home for a maximum of 12 hours before removing them.
11. At the end of treatment, remove the electrodes and inspect the patient's skin for any adverse reactions. Document as appropriate.
12. At the end of the course of treatment any unused unopened bottles of medication are to be returned to Pharmacy.
13. Treatments are generally given every other day and results are typically seen within the first few treatments. If no improvement is seen within four treatments, another modality may be appropriate.
14. Instruct the patient to continue to monitor the area and themselves for any adverse reactions to the medication/procedure. If adverse reactions occur, the patient should notify the department or report to the Emergency Room depending on the severity of the reaction. If the department is notified of the reaction, the treating therapist is to document the reaction, notify the physician, monitor the patient and either discharge or modify the modality. If the patient reports to the Emergency Department, the hospital is to notify the physician. The modality will be discharged from the plan of care.
15. Contraindications to Iontophoresis:
 - a. Allergies or sensitivities to the drug being administered
 - b. Pacemaker (internal or external)
 - c. Implanted defibrillator
 - d. Skin abrasions, lacerations, burns
 - e. Recent scar tissue
 - f. In the temporal or orbital regions
 - g. Current pathway should not cross the heart or brain.
16. Polarity of common medication used in iontophoresis: Medication Polarity
 - a. Dexamethasone negative
 - b. Lidocaine negative

V. REFERENCES

Iontophoresis Unit Manual
Modalities in Physical Therapy

Policy Title	Iontophoresis Monitoring	Policy #	REHAB1931
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VI. STAKEHOLDERS

Physical Therapist, Occupational Therapist

Policy Title	Patient Discharge	Policy #	REHAB1928
Responsible	Director of Rehabilitation Services	Revised/Reviewed	03/21/2023

I. PURPOSE

To provide guidelines for discharge from treatment.

II. POLICY

Rehabilitation Services Department will initiate discharge planning processes for all patients as early in the patient's treatment course as practicable. Discharge planning is initiated at the inception of all rehabilitation services and modified accordingly based on continuing patient assessments. Discharge plans will be patient specific, varying according to age, functional level, treatment setting, and hospital guidelines.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Inpatients: Through continuing assessments, functional reassessments and evaluations of patient progress, discharge plans will be formulated with the patient, utilizing the following guidelines:
 - a. Plans for discharge will be formulated in a collaborative manner with the patient/family and the interdisciplinary team (physician, case manager, nurse, discharge planner).
 - b. Consideration will be given to age, disability, home environment support and treatment setting factors.
 - c. Consideration of the patient's home and work environment will be made upon initial admission to allow for formulation of early plans for discharge.
 - d. When necessary, the Social Worker and/or Discharge Planner will be requested to provide equipment for home use or a list of outside community resources for the patient in the home environment.
2. Patient education/teaching related to discharge plans will be instituted as soon as the discharge plans are formulated and throughout the patient's use of rehabilitation services.
3. Patient education/teaching related to discharge plans will be instituted as soon as the discharge plans are formulated and throughout the patient's use of rehabilitation services.
4. The patient/family will be made aware of a tentative discharge from service date and informed in a timely fashion of any revisions in the date according to the patient's progression with the rehabilitative services treatment plan.
5. The plan of care will be discontinued and the patient transferred/discharged when one or more of the following occur:
 - a. The patient has fully met goals established in the treatment plan by the licensed therapist.
 - b. The patient fails to meet goals after attempt at goal modification, if a plateau has been reached or there is no reasonable expectation of further progress as a direct result of continued skilled therapy.
 - c. The patient's further progress can be met as a result of non-skilled therapy interventions, i.e. restorative nursing, continued self-initiative and/or caregiver's assistance.
 - d. The patient has been discharged from the hospital and no orders have been received to continue treatment as an outpatient.

Policy Title	Patient Discharge	Policy #	REHAB1928
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- e. The patient refuses to continue therapy or fails to comply with the treatment program and does not improve compliance with counseling from clinical staff.
 - f. The patient fails to benefit from therapy as a result of poor tolerance, cognitive deficits, dementia or other conditions or circumstances in which continued skilled therapy becomes ineffective and merely repetitious.
 - g. The patient is transferred to a higher level of care and there are no orders to continue therapy.
 - h. The patient is not making progress and collaborative team efforts recommends discharge from service.
 - i. The physician discontinues treatment.
 - j. The patient becomes disruptive to the care of other patients in the treatment program.
 - k. The patient is seeking alternative care that in combination with the physical medicine program would place him/her at risk for injury, complications or over treatment.
 - l. The patient requires services or skills not available in the department and the patient is referred to a provider who is able to provide these services.
6. Discharge documentation from outpatient services includes, but is not limited to the following:
- a. Discharge summary written by the therapist.
 - b. Summary of services provided and progress, including goals met.
 - c. Reason for discharge.

V. REFERENCES

APTA Clinical Practice Guidelines

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Speech Therapists

Policy Title	Transporting Patients to and from the Rehab Dept	Policy #	REHAB1929
Responsible	Rehab Services	Revised/Reviewed	12/2022

I. PURPOSE

- A. To provide guidelines for transporting the patient in a safe, efficient and comfortable method.
- B. To provide dignity and privacy for all patients.

II. POLICY

- A. All Rehabilitation Department personnel are responsible for the proper transportation and transfer of patients to and from the Rehabilitation Department.
- B. Rehabilitation Department personnel will follow guidelines set forth in the hospital policy for patient transfer.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. When transporting wheelchair patients utilize a robe or other protective garb, and/or a blanket draped over their legs. Use caution to prevent blanket from becoming caught in the wheels. Gurney patients should be covered with a bath blanket, with the seat belt secured or side rails up.

B. Gait training patients must be dressed in appropriate street clothes or have a protective gown to prevent exposure. Patient gown is recommended.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

Policy Title	Summary Sheet for Outpatient Therapy Services	Policy #	REHAB1728
Responsible	Director of Rehabilitation	Revised/Reviewed	3/6/2023

I. PURPOSE

To ensure that all patients receive appropriate care based on their individual needs.

II. POLICY

All new patients presenting to WCH's Outpatient Rehabilitation Department for treatment will complete an initial summary sheet indicating past medical history and patient's goal for therapy.

III. DEFINITIONS

NA

IV. PROCEDURE

1. Upon arrival at the Rehabilitation Department at WCH, the patient will complete a detailed summary sheet identifying past medical history as well as pertinent information necessary to develop an individualized plan of care for their specific needs.
2. The summary sheet will be provided in English or Spanish versions. If the patient has difficulty understanding or completing the forms, the therapist or a clerical staff member will assist in the completion of the appropriate paperwork.
3. This completed summary sheet will be placed in the patient's records to be kept in the Rehabilitation Department with the therapist's initials and date the information was entered.
4. Any changes in the patient's medications during the course of therapy treatment will be added to the patient summary list with the date of notification of the change. Daily documentation must include:
 - a. Changes in medication.
 - b. Signs and symptoms of abuse.
 - c. Pain level at beginning and end of treatment session.

V. REFERENCES

NA

VI. STAKEHOLDERS

Occupational Therapists, Physical Therapists, Physical Therapy Assistants, Speech Therapists

Policy Title	Cleaning Isolation Patient Room-Discharge/Transfer	Policy #	EVS8027
Responsible	EVS	Revised/Reviewed	4/6/23

I. PURPOSE

To provide guidelines for appropriate cleaning of isolation patient rooms after a patient has been discharged or transferred.

II. POLICY

All isolation patient rooms will be cleaned when a patient has been discharged or transferred.

III. DEFINITIONS

IV. PROCEDURE

- A. The patient care unit will notify the Environmental Services Department when the patient has left the premises.
 1. The Environmental Services Department will clean the room as soon as possible.
 - a. If airborne precautions room, wait 20 minutes before entering room wearing appropriate PPE.
- B. Environmental Services Department Staff will:
 1. Put on personal protective equipment (PPE) at the entrance of the room per the isolation guideline posted (i.e., gloves, mask, gown).
 2. Empty all waste containers.
 - a. The waste containers will be wiped out with a hospital approved germicidal solution, all isolation rooms to be disinfected with highest level disinfection solution available to EVS team (**Clostridium Difficile [C-Diff] isolation requires 1:10 bleach solution or hospital approved solution equivalent**) inside, outside and bag liners replaced.
 - b. Emptied waste will be deposited in the appropriate container; red waste bags will be placed in bio-hazardous waste receptacles and clear bags will be placed in regular waste receptacles.
 3. Strip the bed of linen by rolling toward the center of the bed.
 - a. Hold linens away from the body.
 - b. Place linens in the soiled linen container.
 - c. Damp wipe the bed frame (top to bottom, head to foot, left to right) both sides of the mattress, pillows, bed rails and bed control with hospital approved germicidal solution (C-Diff isolation requires 1:10 bleach solution or hospital approved solution equivalent).
 - d. Use clean linens to remake the bed after all disinfecting & cleaning has been completed.
 4. Dust all fixtures, ledges and surfaces in the room and bathroom above shoulder height.
 - a. Begin at the door and work clockwise around the room.
 5. Wash with hospital approved germicidal solution: all spots and hand contact areas including, but not limited to, over bed tables, bedside tables, telephone, chairs, stools, door handles, ledges, light switches, lamps and spots on walls or cabinets including inside drawers. (**C-Diff isolation requires 1:10 bleach solution or equivalent**).
 - a. Work clockwise around the room.

Policy Title	Cleaning Isolation Patient Room-Discharge/Transfer	Policy #	EVS8027
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6. Change curtain (again after all disinfecting & cleaning has been completed) privacy curtain in rooms with C-diff patients. Change curtains in all other rooms as needed if soiled.
7. Dust mop floor as per procedure (depending on floor covering).
8. Clean the bathroom as per procedure.
9. Place wet floor signs at the door to the room.
 - a. Damp mop floor with neutral cleaner.
 - b. Begin at the farthest corner of the room working backwards toward door including the bathroom and closet.
 - c. Be sure to disinfect (mop) baseboards.
10. Remove wet floor signs after the floor has dried completely.
11. When leaving isolation room:
 - a. Wash all supplies and equipment with hospital-approved germicidal solution (C-Diff isolation requires 1:10 bleach solution or hospital approved solution equivalent)
 - b. Place the dirty mop in a bag
 - c. Remove PPE, except for gloves, and dispose of in trash liner.
 - d. Remove gloves and place in trash liner.
 - e. Tie off trash bag.
 - f. Wash hands upon completion of cleaning
12. NOTE: Use a fresh clean cloth in every room.

V. REFERENCES

American Society for Healthcare Environmental Services
<http://www.ashes.org/>

Textbooks:

Practice Guidance for Healthcare Environmental Cleaning
 Practical Application of Disinfections and Sterilization

CDC guidelines for environmental cleaning for MRSA
<http://www.cdc.gov/mrsa/environment/>

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/disinfection_nov_2008.pdf

CDC. Guideline for hand washing and hospital environmental control. MMWR 1998; 37 (no. 24).

Association for Professionals in Infection Control and Epidemiology.
 2009 Volume II, Environmental Services pp. 100: 1-13.

VI. STAKEHOLDERS

Facilities

Policy Title	Cleaning Isolation Patient Room-Occupied	Policy #	EVS8028
Responsible	EVS Director	Revised/Reviewed	4/5/23

I. PURPOSE

To provide guidelines for appropriate daily cleaning of all isolation patient rooms.

II. POLICY

All isolation patient rooms will be cleaned on a daily basis.

III. DEFINITIONS

IV. PROCEDURE

- A. Environmental Services Department Staff will:
 1. Put on personal protective equipment (PPE) at the entrance of the room, per the isolation guidelines posted/required for the type of isolation being entered (i.e., gloves, mask, gown).
 2. Empty all waste containers.
 - a. The waste containers will be wiped out with a hospital approved germicidal solution (**Clostridium Difficile [C-Diff] isolation requires 1:10 bleach solution or hospital approved equivalent**) inside, outside and bag liners replaced.
 - b. Emptied waste will be deposited in the appropriate container; red bag waste will be placed in biohazardous waste receptacles and clear bags will be placed in regular waste receptacles.
 3. Dust all fixtures, ledges and surfaces in the room and bathroom above shoulder height.
 - a. Begin at the door and work clockwise around the room.
 4. Damp wipe with hospital approved germicidal solution: all spots and hand contact areas including, but not limited to, over bed tables, bedrails, bedside tables, telephones, chairs, stools, ledges, light switches, lamps and spots on walls and cabinets. (**C-Diff isolation requires 1:10 bleach solution or hospital approved equivalent**).
 - a. Work clockwise around the room.
 5. Dust mop floor as per procedure.
 6. Clean the bathroom as per procedure.
 7. Place wet floor signs at the door to the room.
 8. Damp mop floor with a hospital-approved germicidal solution(**C-Diff isolation requires 1:10 bleach solution or hospital approved equivalent**).
 - a. Begin at the farthest corner of room working backwards toward door including the bathroom and closet.
 - b. Be sure to disinfect baseboards.
 9. Remove wet floor signs after the floor has dried completely.
 10. When leaving isolation room:
 - a. Wash all supplies and equipment with hospital-approved germicidal solution (**C-Diff isolation requires 1:10 bleach solution or hospital approved equivalent**).
 - b. Place the mop head and linen in a bag
 - c. Remove PPE, except for gloves, and dispose of in trash liner.
 - d. Remove gloves and place in trash bin.

Policy Title	Cleaning Isolation Patient Room-Occupied	Policy #	EVS8028
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- e. Wash hands upon completion of cleaning (use soap and water for handwashing after cleaning isolation room).

11. NOTE: Use a fresh clean cloth in every room

V. REFERENCES

American Society for Healthcare Environmental Services
<http://www.ashes.org/>

Textbooks:

Practice Guidance for Healthcare Environmental Cleaning
 Practical Application of Disinfections and Sterilization

CDC guidelines for environmental cleaning for MRSA
<http://www.cdc.gov/mrsa/environment/>

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/disinfection_nov_2008.pdf

CDC. Guideline for handwashing and hospital environmental control. MMWR 1998; 37 (no. 24).

Association for Professionals in Infection Control and Epidemiology.
 2009 Volume II, Environmental Services pp. 100: 1-13.

VI. STAKEHOLDERS

EVS

Policy Title	MRI Safety General	Policy #	RAD2632
Responsible	VP Ancillary Services <u>Radiology Department</u>	Revised/Reviewed	12/2020 <u>4/18/23</u>

I. PURPOSE

Safety procedures are those actions that provide adequate confidence that the MRI Department provides a safe environment for patients, visitors, physicians, and employees to prevent situations that may be open to accidents or injuries.

II. POLICY

It is the policy of the MRI Department to provide the safest environment for any person who enters the department, be it a visitor, patient, or employee. The MRI Department will continually report unsafe actions, conditions, or practices to the Director of the department.

III. DEFINITIONS

N/A

IV. PROCEDURE

Specific areas of protection relating to magnet safety for all individuals entering the department are reviewed on a constant ongoing basis. The contrast agents and crash cart drugs are reviewed for expiration dating by both Pharmacy and the MRI Department. The MRI equipment is reviewed by a licensed physicist annually and is subject to annual preventative maintenance review by authorized service personnel.

All individuals and patients entering the MR environment will be screened thoroughly by a qualified, trained MR technologist and/or physician using procedures that include a written form and a verbal interview. Any individual accompanying the patient into the MR room, such as a parent, spouse, or friend, must also undergo the screening procedure prior to being exposed to the MR environment.

1. The technologist/nurse must always maintain visual contact with any patient. This would include the pediatric, unconscious, or sedated patient.
2. No ferrous or other magnetic objects may be brought into the neighborhood of the magnet. Such objects will be attracted by the magnet with a force many times greater than the earth's gravity force. This could cause serious or fatal injury to staff, ~~patient~~patients, or visitors; it could also cause damage to the equipment. For safety, MRI technologist will use a handheld metal detector to scan all patients prior to entering zone 4, the room where the magnet is located. Any objects in question must be examined with our hand-held metal detector before being brought into the magnetic field.
3. The technologist must be aware that the patient may experience oppressive effects when moved in the vicinity of the magnet. Failure to act on those effects could cause patient injury or equipment damage.
4. Always apply hearing protection to the patient and any anyone else present in the scanning room before beginning the procedure.
5. Before starting any procedure that will require table movement, check the patient, clothing, cables, IV lines and other equipment and accessories for the possibility of getting caught or hitting anything during table movement.
6. The technologist must inform the patient about the possibility of system components warming up during scanning. This includes RF coils and interface boxes.
7. The MRI Controlled Access Area will be locked any time the MRI Technologist or qualified service personnel is not present.

Policy Title	MRI Safety General	Policy #	RAD2632
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V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A



Board Report

Meeting Date: April 26, 2022

Report Type: Consent

Title: Conflict of Interest Code (Code)

Recommendation: Pass a **Resolution** adopting the Pajaro Valley Health Care District Hospital Corporation Conflict of Interest Code pursuant to the Political Reform Act of 1974.

Contact: Matko Vranjes, Interim Chief Executive Officer

Executive Summary

The Political Reform Act (the “Act”) requires all state and local government agencies to adopt and promulgate a Conflict of Interest code establishing the rules for reporting personal assets and the prohibition from making or participating in the making of any decisions that may affect any personal assets. A Conflict of Interest code must specifically designate all agency positions, except for those listed in Gov. Code § 87200, that make or participate in the making of agency decisions which may foreseeably have an effect on any financial interest of that person and assign specific types of personal assets to be disclosed that may be affected by the exercise of powers and duties of that position.

Analysis

The attached Conflict of Interest Code incorporates FPPC Regulation 18730 by reference as the provisions with an Appendix attached designating positions that make or participate in making decisions of the agency and assigned appropriate disclosure categories in Exhibit “A,” and list the disclosure categories in Exhibit “B”, as well as declare those primary positions that specifically manage public investments. This is commonly referred to as the FPPC Standard Code.

On March 6, 2023, the Notice of Intent was emailed to proposed filers and posted at Kathleen King Community Room - 85 Nielson Street, Watsonville.

Financial Impact: None

Attachments:

B-Conflict of Interest Code with Appendix A & B

C-Explanation of Filers

D-Email to Filers-Notice of Intention

RESOLUTION NO.

RESOLUTION OF THE BOARD OF DIRECTORS OF THE PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION ADOPTING A CONFLICT OF INTEREST CODE PURSUANT TO THE POLITICAL REFORM ACT OF 1974

WHEREAS, the State of California enacted the Political Reform Act of 1974, Government Code Section 81000 et seq. (the "Act"), which contains provisions relating to conflicts of interest which potentially affect all officers, employees and consultants of the Pajaro Valley Health Care District Hospital Corporation (the "Corporation") and requires all public agencies to adopt and promulgate a conflict of interest code; and

WHEREAS, the potential penalties for violation of the provisions of the Act are substantial and may include criminal and civil liability, as well as equitable relief which could result in the Corporation being restrained or prevented from acting in cases where the provisions of the Act may have been violated; and

WHEREAS, notice of the time and place of a public meeting on, of consideration by the Board of Directors of, the proposed Code was provided each affected designated position and publicly posted by the Corporation, establishing a 45-day comment period in compliance with Title 2, California Code of Regulations, Section 18750; and

WHEREAS, a public meeting was held upon the proposed Code at a regular meeting of the Board of Directors on April 26, 2023, at which all present were given an opportunity to be heard on the proposed Code.

NOW, THEREFORE, BE IT RESOLVED by the Board of Directors of the Pajaro Valley Health Care District Hospital Corporation as follows:

Section 1. The Board of Directors does hereby adopt the proposed Conflict of Interest Code, a copy of which is attached hereto and shall be on file with the Executive Assistant of the Corporation, and available to the public for inspection and copying during regular business hours.

Section 2. The Conflict of Interest Code shall be submitted to the Fair Political Practices Commission ("FPPC") for approval and said Code shall become effective 30 days after the FPPC approves the proposed Conflict of Interest Code.

Section 3. All previously adopted conflict of interest codes are hereby rescinded.

PASSED AND ADOPTED this 26th day of April 26, 2023, by the following vote:

AYES:

NOES:

ABSTAIN:

ABSENT:

APPROVED:

Chair, Board of Directors
Pajaro Valley Health Care District

ATTEST:

Secretary, Board of Directors
Pajaro Valley Health Care District

CONFLICT OF INTEREST CODE
OF THE
PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

The Political Reform Act (Government Code Section 81000, et seq.) requires state and local agencies to adopt and promulgate conflict of interest codes. The Fair Political Practices Commission has adopted a regulation (2 Cal. Code of Regulations section 18730) that contains the terms of a standard conflict of interest code, which can be incorporated by reference in an agency's code. After public notice and hearing the standard code may be amended by the Fair Political Practices Commission to conform to amendments in the Political Reform Act. Therefore, the terms of 2 California Code of Regulations section 18730 and any amendments to it duly adopted by the Fair Political Practices Commission are hereby incorporated by reference. This regulation and the attached Appendix designating positions and establishing disclosure categories, shall constitute the conflict of interest code of the **Pajaro Valley Health Care District Hospital Corporation ("Hospital Corporation")**.

All officials and designated positions shall file their statements of economic interests with the **Executive Assistant** as the Hospital Corporation's Filing Officer/Official. The **Executive Assistant** shall make all statements available for public inspection and reproduction. (Gov. Code Section 81008.) All statements will be retained by the **Hospital Corporation**.

APPENDIX

CONFLICT OF INTEREST CODE

OF THE

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION

PART “A”

OFFICIALS WHO MANAGE PUBLIC INVESTMENTS

District Officials who manage public investments, as defined by 2 Cal. Code of Regs. § 18700.3(b), are NOT subject to the Hospital Corporation’s Code, but must file disclosure statements under Government Code Section 87200 et seq. [Regs. § 18730(b)(3)] These positions are listed here for informational purposes only.

It has been determined that the positions listed below are officials who manage public investments¹:

Members of the Board of Directors and their Alternates

Chief of Executive Officer

Chief Financial Officer

Controller

¹

Individuals holding one of the above-listed positions may contact the Fair Political Practices Commission for assistance or written advice regarding their filing obligations if they believe that their position has been categorized incorrectly. The Fair Political Practices Commission makes the final determination whether a position is covered by Government Code Section 87200.

DESIGNATED POSITIONS

GOVERNED BY THE CONFLICT OF INTEREST CODE

<u>DESIGNATED POSITIONS'</u> <u>TITLE OR FUNCTION</u>	<u>DISCLOSURE CATEGORIES</u> <u>ASSIGNED</u>
Chief Financial Officers (ALL)	1, 2
Chief Human Resources Officer	5
Chief Nursing Officer	5
Chief Operating Officer	1, 2
Clinical Nurse Manager, Wound Care	5
Compliance and Risk Manager	5, 6
Director of Clinic Operations	5
Director of Continuum Care	5
Director of Education	5
Director of Emergency Services	5
Director of Facilities	5
Director of HIM	5
Direction of Infection Control	5
Director of Lab	5
Director of Marketing, Growth & Outreach Director	5
Director of Medical Staff	5
Director of Nursing Services (MedSurg/Tele/ICU)	5
Director of Nutrition Services	5
Director of Perinatal Services	5
Director of Perioperative Services	5
Director of Pharmacy	5

DESIGNATED POSITIONS'
TITLE OR FUNCTION

DISCLOSURE CATEGORIES
ASSIGNED

Director of Quality & Risk	5, 6
Director of Revenue Cycle	1, 2
Finance Manager	1, 2
Manager of Information Services	5
Manager of Revenue Cycle	1, 2
Nursing Manager	5
Patient Access Manager	5
Radiology Manager	5

Consultants and New Positions*

*Individuals providing services as a Consultant defined in Regulation 18700.3, or in a new position created since this Code was last approved that makes or participates in making decisions, as identified in Reg. 18734, shall disclose pursuant to the broadest disclosure category in this Code subject to the following limitation:

The Chief Executive Officer may determine that due to the range of duties or contractual obligations, it is more appropriate to assign a limited disclosure requirement. A clear explanation of the duties and a statement of the extent of the disclosure requirements must be in a written document. (Gov. Code Sec. 82019; FPPC Regulations 18219 and 18734.) The Chief Executive Officer's determination is a public record and shall be retained for public inspection in the same manner and location as this Conflict of Interest Code. (Gov. Code Sec. 81008.)

PART “B”

DISCLOSURE CATEGORIES

The disclosure categories listed below identify the types of economic interests that the Designated Position must disclose for each disclosure category to which the designated is assigned. “Investment” means financial interests in any business entity (including a consulting business or other independent contracting business) and are reportable if they are either located in or doing business in the jurisdiction, are planning to do business in the jurisdiction, or have done business during the previous two years in the jurisdiction of the Hospital Corporation. This Conflict of Interest Code does not require the reporting of gifts from outside this Hospital Corporation’s jurisdiction if the source does not have some connection with or bearing upon the functions or duties of the position. (Reg. 18730.1)

Category 1: All investments and business positions in business entities, and sources of income, including gifts, loans and travel payments, that are located in, do business in, or own real property within the jurisdiction of the Hospital Corporation.

Category 2: All interests in real property which is located in whole or in part within, or not more than two (2) miles outside, the jurisdiction of the Hospital Corporation, including any leasehold, beneficial or ownership interest or option to acquire property.

Category 3: All investments and business positions in business entities, and sources of income, including gifts, loans and travel payments, that are engaged in land development, construction or the acquisition or sale of real property within the jurisdiction of the Hospital Corporation.

Category 4: All investments and business positions in business entities, and sources of income, including gifts, loans and travel payments, that provide services, products, materials, machinery, vehicles or equipment of a type utilized by the Hospital Corporation.

Category 5: All investments and business positions in business entities, and sources of income, including gifts, loans and travel payments, that provide services, products, materials, machinery, vehicles or equipment of a type purchased or leased by the Designated Position’s Department.

Category 6: All investments and business positions in business entities, and sources of income, including gifts, loans, and travel payments, if such entities or sources have filed claims against the Hospital Corporation in the past 2 years, or have a claim pending before the Hospital Corporation.

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION
CONFLICT OF INTEREST CODE

ADOPTED _____, BY
RESOLUTION NO. _____

PAJARO VALLEY HEALTH CARE HOSPITAL CORPORATION

HOSPITAL CORPORATION

EXPLANATION OF DESIGNATION OF POSITIONS AND THE ASSIGNMENT OF DISCLOSURE REQUIREMENTS

Pursuant to Government Code sections 87300 and 87303, as well as 2 California Code of Regulations section 18750.1, the Pajaro Valley Health Care Hospital Corporation Hospital Corporation (the "Hospital Corporation") has proposed its initial Conflict of Interest Code (the "Code"). The Code must designate those employees, members, officers, and consultants who make or participate in the making of decisions which may foreseeably have a material effect on a financial interest and are therefore, subject to the disclosure and disqualification requirements of the Code.

The Code must also set forth Disclosure Categories to be assigned to the designated positions requiring individuals holding each position to disclose personal interests that may be affected by the exercise of the individual's duties.

Below is an explanation of the specific designations, their disclosure requirements and the requirements of the Disclosure Categories created.

"OFFICIALS WHO MANAGE PUBLIC INVESTMENTS"

The Hospital Corporation has delineated those primary officials determined to fall under the definition of "Officials Who Manage Public Investments" as required by the Fair Political Practices Commission (the "FPPC"). The Code does not establish disclosure requirements for these officials as specified in Gov. Code Section 87200.

The positions meeting the definition of "Officials Who Manage Public Investments" have full disclosure requirements under Section 8720 and are as follows:

Members, Board of Directors and their Alternates: The Board is the primary body responsible for "formulating or approving investment policies," a pivotal component of the management of public funds. [§18700.3]. Therefore, it has been determined that the Members of the Board of Directors and their Alternates meet the definition of "officials who manage public investments." Pursuant to Section 18700.3, these officials are subject to the conflict-of-interest provisions of the Political Reform Act (the "Act") and have full disclosure responsibilities.

Chief of Executive Director: The Executive Director is the primary Officer responsible to and who works with the Board in "formulating or approving investment policies," and "approving or establishing guidelines" for asset allocations. This position

is also the primary Officer responsible for "directing" and/or "approving" investment transactions and requirements. These are all the critical elements in the management of public funds. [§18700.3]. Therefore, it has been determined that this Officer meets the definition of "officials who manage public investments." Pursuant to Section 18730(b)(3), this official is subject to the conflict of interest provisions of the Act and has full disclosure responsibilities.

Chief Financial Officer. The Chief Financial Officer is an Officer responsible to and who works with the Board in "formulating or approving investment policies," and "approving or establishing guidelines" for asset allocations. This position is an Officer responsible for "directing" and/or "approving" investment transactions and requirements. These are all the critical elements in the management of public funds. [§18700.3]. Therefore, it has been determined that this Officer meets the definition of "officials who manage public investments." Pursuant to Section 18730(b)(3), this official is subject to the conflict of interest provisions of the Act and has full disclosure responsibilities.

Controller. The Controller is an Officer responsible to and who works with the Board in "formulating or approving investment policies," and "approving or establishing guidelines" for asset allocations. This position is also an Officer responsible for "directing" and/or "approving" investment transactions and requirements. These are all the critical elements in the management of public funds. [§18700.3]. Therefore, it has been determined that this Officer meets the definition of "officials who manage public investments." Pursuant to Section 18730(b)(3), this official is subject to the conflict of interest provisions of the Act and has full disclosure responsibilities.

Investment Consultant: This generic position has been added to cover contracting with consultants that specifically advise in portfolio development and investments, or fall under other elements of the definition of the "management of investments."

“DESIGNATED POSITIONS”

The Hospital Corporation's list of Designated Positions specifically enumerates all positions within the Hospital Corporation which make or participate in the making of Hospital Corporation decisions which may foreseeably have a material effect on that position's financial interests.

Disclosure Categories have been assigned to the Designated Positions on a narrow basis in relation to their official duties with the Hospital Corporation to prevent requiring over disclosure.

Positions that, by virtue of their positions, are involved in all facets of Hospital Corporation operations have been assigned Categories 1 and 2 indicating "full disclosure" requirements. Likewise, positions having narrower involvement and/or responsibilities with the Hospital Corporation have been assigned more limiting disclosure requirements based on the duties of the position. (See Explanation of Types of Disclosure Categories, below.)

Chief Financial Officers (ALL) - 1, 2

Added with full disclosure. This position is involved in a broad range of Hospital Corporation decisions too numerous and varied to narrow.

Chief Human Resources Officer - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Chief Nursing Officer – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Chief Operating Officer – 1, 2

Added with full disclosure. This position is involved in a broad range of Hospital Corporation decisions too numerous and varied to narrow.

Clinical Nurse Manager, Wound Care – 5

This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Compliance and Risk Manager - 5, 6

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities in development, implementation and management of risk and safety programs, including risk assessment and recommendations to prevent risks; identify and manage program insurance requirements and make recommendations for liability and claims, reducing identified risks; provide contract language and insurance requirements; and handle certain claim matters.

Director of Clinical Operations – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Continuum Care - 5

This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Education - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Emergency Services - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Facilities - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of HIM - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Infection Control – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Lab - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Marketing, Growth & Outreach- 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Medical Services - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Nutrition Services - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Nursing Services (MedSurg/Tele/ICU) - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Perinatal Services – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Perioperative Services – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Pharmacy – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Director of Quality & Risk - 5, 6

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities in development, implementation and management of risk and safety programs, including risk assessment and recommendations to prevent risks; identify and manage program insurance requirements and make recommendations for liability and claims, reducing identified risks; provide contract language and insurance requirements; and handle certain claim matters.

Director of Revenue Cycle – 1, 2

Added with full disclosure. This position is involved in a broad range of Hospital Corporation decisions too numerous and varied to narrow.

Finance Manager – 1, 2

Added with full disclosure. This position is involved in a broad range of Hospital Corporation decisions too numerous and varied to narrow.

Manager of Information Services - 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Manager of Revenue Cycle – 1, 2

Added with full disclosure. This position is involved in a broad range of Hospital Corporation decisions too numerous and varied to narrow.

Nursing Manager – 5

Added with limited disclosure based on duties with Hospital Corporation. This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Patience Access Manager – 5

This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Radiology Manager - 5

This position makes and participates in making governmental decisions with responsibilities are limited to interests in entities that provide services, supplies, etc. of the typed used by a Designated Position's department, division or unit.

Consultants and New Positions

Consultants is a generic designated position to cover any contracted positions not specifically designated meeting the definition of Consultant under the Political Reform Act and required to file disclosure statements because they may make, participate in making or influence decisions, as defined.

New Positions covers any newly created positions for interim filing requirements pending amendment of the Code.

Consultants and New Positions have specific language appended to them indicating that these positions have full disclosure responsibilities unless specifically narrowed or waived, in writing, by the Executive Director, based on their duties and placed on file with the Hospital Corporation's Filing Officer. Identification of New Positions and Consultants will be done on FPPC Forms 804 and 805, respectively, and place on file with the Hospital Corporation's Filing Officer.

EXPLANATION OF DISCLOSURE CATEGORIES

Disclosure Categories identify the types of investments, business entities, sources of income, including gifts, loans and travel payments, or real property which the Designated Employee must disclose for each disclosure category to which he or she is assigned.

The Hospital Corporation cannot require a Designated Position to over-disclose. Disclosure Categories must be designed and assigned **depending on the duties and responsibilities of the position held**. Therefore, five Disclosure Categories have been designed to be assigned to the various designated positions listed in Part "A" of the Appendix to the proposed Code. This list of Disclosure Categories provides flexibility in the application of the various Categories to the different designated positions but are narrow enough so as not to require over-disclosure by a Designated Position or Consultant.

ASSIGNMENT OF DISCLOSURE CATEGORIES:

Category 1 requires the disclosure of reportable investments, business positions, and sources of income in the jurisdiction of the Hospital Corporation.

Category 2 requires the disclosure of reportable interests in all real property (not including personal residence) located in the jurisdiction of the Hospital Corporation (or within 2 miles thereof).

The assignment of Categories 1 and 2 means the Designated Position has full disclosure requirements of reportable interests that own real property, are located in, do business in or have done business in the Hospital Corporation's jurisdiction in the past two years of filing a statement. These Categories are usually assigned to General Counsel, and other very broad decision-makers whose responsibilities are too broad to be narrowed and warrant full disclosure. These are also the disclosure requirements provided Consultants, as defined, and New Positions if not narrowed in writing as described above, in Forms 804 and 805.

Category 3 is limited to interests in entities involved in land development, construction or buying/selling real property. This is usually assigned narrowly to such positions as planners or engineers, or other project managers.

Category 4 is limited to interests in entities that provide services, supplies, etc. of the type used by the Agency. This Category is reserved for positions that are involved in the Hospital Corporation on a broad basis touching a variety of departments and are therefore, unable to be narrowed to one department, division or area. Positions assigned this Category are usually involved in broad areas of administration and fiscal services.

Category 5 is limited to interests in entities that provide services, supplies, etc. of the type used by a Designated Position's department, division or unit. This Category is assigned to positions involved in limited aspects of the Hospital Corporation so that disclosure requirements can be narrowed to the position's specific area in order to avoid requiring over-disclosure. This Category is also used to assign to Consultants in specific areas.

Category 6 is limited to interests in entities and sources if such have filed claims against the Hospital Corporation in the past 2 years, or have a claim pending before the Hospital Corporation. Positions assigned this Category are usually involved with handling or making recommendations regarding claims filed against the agency.

Notification to Filers

Emailed: March 6, 2023 @ 11:36 am

As required by law, I hereby give notice that the Board of Directors of the Pajaro Valley Health Care District Hospital Corporation intends to adopt a Conflict of Interest Code pursuant to Government Code Section 87300. The Notice of Intention will be posted no later than March 10, 2023.

Attached is:

- **Copy of Notice of Intention**
- **Draft Conflict of Interest Code**
- **Explanation of Filers**
- **Basic Rule and Guide to Conflict of Interest Regulations** [Fair Political Practices Commission, Title 2, Division 6, California Code of Regulations § 18700]

Regards,
Dawn Bullwinkel
Consultant Clerk of the Board

**PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION
NOTICE OF INTENTION TO ADOPT A
CONFLICT OF INTEREST CODE**

NOTICE IS HEREBY GIVEN that the Board of Directors of the **Pajaro Valley Health Care District Hospital Corporation** intends to adopt a Conflict of Interest Code pursuant to Government Code Section 87300.

A conflict of interest code designates those employees, members, officers and consultants who make or participate in the making of governmental decisions which may affect their financial interests, who must disclose those interests in financial disclosure statements, and who must disqualify themselves from making or participating in the making of governmental decisions affecting those interests.

The proposed Conflict of Interest Code will be considered by the Board of Directors on April 26, 2023, at 5:00 pm. Any interested person may be present electronically and comment at the public meeting or may submit written comments concerning the proposed amendment. No public hearing on this matter will be held unless an interested person or his or her representative requests a public hearing no later than April 11, 2023, 15 days prior to the close of the written comment period. Any comments or inquiries should be directed to the attention of Dawn Bullwinkel, Consultant Board Clerk, at info@pvhcd.org. Written comments must be submitted no later than April 26, 2023 at 5:00 p.m.

Copies of the proposed Code may also be obtained at Watsonville Community Hospital, Executive Offices, 75 Neilson Street, Watsonville, CA.



Board Report

Meeting Date: April 26, 2023

Report Type: Consent

Title: Limited Authority Retirement Plan Amendments

Recommendation: Pass a **Resolution** authorizing the delegation of limited “settlor” authority to the Chief Human Resources Officer (CHRO) to make certain types of plan amendments.

Contact: Allyson Hauck, Chief Human Resources Officer

Background/Situation/Rationale

Watsonville Community Hospital (“Hospital”) has established and maintains the Watsonville Community Hospital 401(a) Plan, the Watsonville Community Hospital 457(b) Plan, the Watsonville Community Hospital Defined Contribution Plan For Service and Maintenance Unit of SEIU United Healthcare Workers – West, and the Watsonville Community Hospital Cash Balance Pension Plan (collectively, the “Plans”) for various eligible employees of the Hospital. Although the Board has previously delegated “administrative” responsibility over the Plans to the CHRO it has retained authority under the Plan documents to amend the terms of the Plans.

Due to the complexities of the Plans and due to a number of recent law changes (e.g., the Secure Act and the Secure 2.0 Act), it has become necessary and desirable to make “minor” amendments to the Plans to facilitate plan administration and to take advantage of new law changes that would provide more flexibility to Plan participants. For example, in December 2022, staff requested and obtained Board authorization to amend the Watsonville Community Hospital 401(a) Plan to make minor changes to the Plan’s eligibility provisions. Now, due to the recent passage of the Secure 2.0 Act, the Hospital Corporation will have numerous opportunities over the coming months and years to make “no-cost” changes to its Plans, which will provide enhanced choice and flexibility to Plan participants. One such change would allow participants in the 457(b) Plan to change their salary deferral elections at almost any time, rather than during the calendar month prior to the change.

As stated in the attached resolution, the “limited” authority to amend the Plans will only be for the following purposes: (i) to conform a Plan’s terms to applicable law; (ii) to clarify a Plan’s intended operation; (iii) to implement any directive of this Board; or (iv) to make any other changes to a Plan that the CHRO finds necessary or desirable, but only to the extent that any such changes do not result in a material increase in any Plan’s costs or materially limit the benefits available to participants under any Plan.

In addition, the attached resolution will ratify the actions of the CHRO and management to make a minor, but urgent, minor amendment to the 401(a) Plan for the purpose of allowing participants to borrow from their own participant accounts up to the maximum amount permitted by the tax code.

Pajaro Valley Health Care District Hospital Corporation (PVHCDHC)

This change was made by management in response to an “urgent” request by participants to be able to borrow the same amounts they would have been able to borrow from most employers’ plans.

Timeline/Process to date:

If the resolution is approved, the CHRO will have immediate authority to make any amendments described in the delegation.

Financial Impact:

Negligible. Only amendments that do not materially increase any Plan’s costs are within the scope of the delegation.

Implementation of this delegation will give management and staff greater ability to keep the Plans up to date and more easily administered.

Attachments:

A: Resolution

B: Hospital 401(a) Plan

**BEFORE THE BOARD OF DIRECTORS
OF THE PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION**

RESOLUTION NO

**RESOLUTION AUTHORIZING CHIEF HUMAN RESOURCE OFFICER (CHRO) TO MAKE
CERTAIN LIMITED RETIREMENT PLAN AMENDMENTS**

WHEREAS, the Pajaro Valley Health Care District Hospital Corporation (“Hospital”) has established and maintains the Watsonville Community Hospital 401(a) Plan, the Watsonville Community Hospital 457(b) Plan, the Watsonville Community Hospital Defined Contribution Plan For Service and Maintenance Unit of SEIU United Healthcare Workers – West, and the Watsonville Community Hospital Cash Balance Pension Plan (collectively, the “Plans”) for certain eligible employees of the Hospital; and

WHEREAS, the Hospital has reserved the right to amend the Plans at any time in accordance with terms of the Plans’ documents; and

WHEREAS, to ensure that participants of the Plan have access to updated features and benefits provided by applicable laws and regulations in a timely manner, and to ensure compliant and cost-effective administration of the Plans, staff recommends delegating certain settlor authority related to the amendment of the Plans to the CHRO; and

WHEREAS, the board of the Hospital deems it to be the best interests of the Hospital and the Plan’s participants to delegate certain settlor authority regarding the amendment of the Plans to the CHRO;

WHEREAS, the CHRO, following consultation with the Hospital’s special employee benefits counsel, has taken action to amend the 401(a) to increase the amount of available as a participant loan, in response to an urgent participant request, and such amendment would fall squarely with the delegation being authorized by this Resolution;

NOW, THEREFORE, THE BOARD OF DIRECTORS OF THE PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION HEREBY RESOLVES AND ORDERS AS FOLLOWS:

Section 1. The foregoing recitals are adopted as findings of the Board of Directors as set forth within the body of this Resolution.

Section 2. Effective immediately, the Board of delegates to the CHRO the authority to adopt amendments to the Plans for any of the following purposes: (i) to conform a Plan's terms to applicable law; (ii) to clarify a Plan's intended operation; (iii) to implement any directive of this Board; or (iv) to make any other changes to a Plan that the CHRO finds necessary or desirable, but only to the extent that any such changes do not result in a material increase in any Plan's costs or materially limit the benefits available to participants under any Plan.

Section 3. The recent amendment made by the CHRO and management to increase the participant loan limit for the 401(a) Plan is approved and ratified.

Section 4. Staff is authorized and directed to take all such other necessary or appropriate actions to implement the intent and purposes of this Resolution.

PASSED AND ADOPTED by the Board of Directors of the Pajaro Valley Health Care District this _ day of _ 2023, by the following vote:

AYES:

NOES:

ABSENT:

ABSTAIN:

Chair, Board of Directors

ATTEST:

Clerk of the Board

APPROVED AS TO FORM:

District Counsel

ADOPTION AGREEMENT

FOR

WATSONVILLE COMMUNITY

HOSPITAL 401(a) PLAN

(AS OF APRIL 17, 2023)

TABLE OF CONTENTS

A.	ADOPTION AGREEMENT STATUS	2
B.	EMPLOYER	2
C.	PLAN NAME AND PLAN NUMBER	2
D.	EFFECTIVE DATE	2
E.	YEARLY DATE	2
F.	FISCAL YEAR	3
G.	NAMED FIDUCIARY	3
H.	PLAN ADMINISTRATOR	3
I.	PREDECESSOR EMPLOYER AND PRIOR EMPLOYER	3
J.	ELIGIBLE EMPLOYEE	4
K.	ENTRY REQUIREMENTS AND ENTRY DATE	6
L.	HIGHLY COMPENSATED EMPLOYEE AND TESTING METHODS	8
M.	COMPENSATION	9
N.	EMPLOYER CONTRIBUTIONS AND FORFEITURES	11
O.	NET PROFITS AND CONTRIBUTION REQUIREMENTS	17
P.	CONTRIBUTION MODIFICATIONS	18
Q.	REQUIRED CONTRIBUTIONS AND OPTIONAL CONTRIBUTIONS	19
R.	VOLUNTARY CONTRIBUTIONS AND ROLLOVER CONTRIBUTIONS	19
S.	INVESTMENTS	19
T.	VESTING PERCENTAGE	21
U.	VESTING SERVICE	22
V.	EQUIVALENCIES	23
W.	WITHDRAWAL BENEFITS	23
X.	RETIREMENT AND THE START OF BENEFITS	24
Y.	FORMS OF DISTRIBUTION FOR RETIREMENT BENEFITS	26
Z.	ADOPTING EMPLOYERS	27
AA.	MERGER OR SPIN-OFF	35

Plan ID No. _____

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ADOPTION AGREEMENT FOR THE WATSONVILLE COMMUNITY

HOSPITAL 401(a) PLAN

INTRODUCTION

The Watsonville Hospital Corporation (the "Predecessor Employer") previously established an Internal Revenue Code ("Code") section 401(k) retirement plan on September 1, 1998 (the "Plan"). The Watsonville Community Hospital Money Purchase Pension Plan was merged into the Plan as of January 1, 2019.

As of December 27, 2021, the Predecessor Employer along with certain related entities involved in the business and operation of the Watsonville Community Hospital ("Hospital") entered into an agreement ("APA") with Pajaro Valley Healthcare District Project ("PVHDP") for PVHDP to purchase the assets, properties, rights, and business operations of the Hospital (collectively, the "Business") and to offer employment to some or all of the Hospital's employees. Effective on or about August 31, 2022, all of PVHDP's rights and obligations under the APA will be assigned and assumed by Pajaro Valley Health Care District Hospital Corporation (the "Employer"). In accordance with the terms of the above-mentioned agreements, the Employer is agreeing to continue the employment of substantially all of the Hospital's employees and to offer these employees, along with any new hires, with retirement benefits that are similar to those previously provided by the Predecessor Employer to the extent possible.

The Employer is considered an instrumentality of local government and any employee benefit plan it sponsors would be considered a "governmental plan" under Code section 414(d) and ERISA section 3(32), such that its retirement plan(s) would be exempt for certain provisions of the Code and ERISA. Furthermore, as a governmental entity, the Employer is not eligible to establish and maintain a Code section 401(k) plan.

The Plan was previously amended and restated as of September 1, 2022, the closing date specified under the Asset Purchase Agreement (APA) entered into between the Hospital and the Project on December 27, 2021. The Employer amended and restated the Plan as of January 1, 2023 in order to clarify certain provisions of the Plan relating to eligibility and to improve the administration of the Plan.

The Employer now wishes to further amend and restate the Plan as of April 17, 2023 (the Effective Date) to increase the amounts that participants can borrow from the Plan as participant loans in accordance with applicable IRS rules.

It is intended that the Plan, as amended, qualify as a profit sharing plan (without a section 401(k) feature) under the Internal Revenue Code of 1986, including any later amendments to the Code that apply to governmental plans. From and after the Effective Date, the Plan will no longer be subject to ERISA to the extent provided in ERISA section 4(b). The Employer agrees to operate the Plan according to the terms, provisions, and conditions set forth in this document.

The amended Plan continues to be for the exclusive benefit of employees of the Employer. All persons covered under the Plan before the effective date of this amendment shall continue to be covered under the amended Plan, if they are still Eligible Employees as of the amendment date, with no loss of benefits.

Any participant under the above-referenced plan(s) who is an Eligible Employee as defined in the DEFINITIONS SECTION of Article I shall continue to be a Participant in this Plan. His entry date under the prior plan shall be deemed to be his Entry Date under this Plan.

(Use black ink to complete the Adoption Agreement.)

Plan ID No. _____

- A. This ADOPTION AGREEMENT together with the attached BASIC DEFINED CONTRIBUTION PLAN FOR THE WATSONVILLE COMMUNITY HOSPITAL 401(a) PLAN constitutes (Select (1), (2), or (3). Select (4), if applicable.)

NOTE: The effective date for a new plan cannot be earlier than the first day of the Plan Year in which this Adoption Agreement is signed. The effective date for an amendment or restatement cannot be earlier than the first day of the Plan Year in which the amended or restated Adoption Agreement is signed.

- 1) ☐ a new plan. (Cannot select if spin-off of an existing plan. See Item AA(2).)
- 2) ☒ a restatement of an existing plan. Such existing plan was qualifiable under Code Section 401(a). Except as provided elsewhere in the Plan, the provisions of this restatement are effective on the effective date described in the Introduction. This is the RESTATEMENT DATE.
- 3) ☐ Amendment No. _____ to the Plan. It replaces all prior amendments to the Plan and the first Adoption Agreement. Except as provided elsewhere in the Plan, the Provisions of this amendment are effective on _____, _____. (Month, day and year.)
- 4) ☐ The Plan is/was frozen effective _____, _____. (Month, day and year. The initial amendment to freeze the Plan must be prospective to comply with Code Section 411(d)(6).)

Note: No Contributions will be made to the Plan and no Employee, former Employee, or Inactive Participant will become an Active Participant after such date.

B. The EMPLOYER is Pajaro Valley Healthcare District Hospital Corporation

(Fill in exact legal name)

C. The PLAN NAME is Watsonville Community Hospital 401(a) Plan

(For example: ABC, Inc. Profit Sharing Plan)

The PLAN NUMBER is 001. (3-digit number used for Form 5500 reporting)

D. The Plan's original EFFECTIVE DATE is September 1, 1998. (Month, day and year)

E. The YEARLY DATE is the first day of each Plan Year. (Fill in the Effective Date. If this is not a new plan and the Yearly Date has changed more than once, fill in any Yearly Date that is not later than the Restatement Date or amendment effective date.)

The Yearly Date is September 1, 1998 (Month, day and year.) and (Select one.)

- 1) ☐ the same day of each following year.
- 2) ☒ each following January 1. (The first Plan Year is short.)
- 3) ☐ each following _____ . (The first Plan Year is short.)
- 4) ☐ (a) each following _____ through
(b) _____, _____ and

Plan ID No. _____

(c) each following _____. (A *later Plan Year* is short. Complete (a) using the same month and day as in Yearly Date above, (b) using the same month and day as in (a) and the calendar year in which the short Plan Year begins, and (c) using the first day of the new Plan Year.)

If the first date in Item E is after the Effective Date, Yearly Dates before the first date in Item E above shall be determined under the provisions of the (Prior) Plan before that date.

F. The FISCAL YEAR is the Employer's taxable year and ends on 12/31.
(Month and day or a specific day of the year such as last Saturday of September.)

G. The Employer is the NAMED FIDUCIARY, unless otherwise specified in (1) below.

1) ☒ The Employer's human resource director _____ is the
Named Fiduciary. (Neither Principal Life Insurance Company nor its affiliates can be named.)

H. The Employer is the PLAN ADMINISTRATOR, unless otherwise specified in (1) below.

1) ☐ The Employer's human resource director _____ is the
Plan Administrator. (Neither Principal Life Insurance Company nor its affiliates can be named.)

If (1) is selected, complete the address, phone number, and tax filing number
of the Plan Administrator.

Address Allyson Hauck, Chief Human Resource Officer
75 Nielson Street
Watsonville, CA 95076

Phone No. _____ Tax Filing No. _____

I. PREDECESSOR EMPLOYER AND PRIOR EMPLOYER.

1) A PREDECESSOR EMPLOYER is a firm of which the Employer was once a part (e.g., due to a spin-off or a change of corporate status) or a firm absorbed by the Employer because of a merger or acquisition (stock or asset, including a division or an operation of such company). No selections are needed for a Predecessor Employer that maintained this Plan since the Employer is defined as including such Predecessor Employer, and service with the Employer would therefore include service with such Predecessor Employer.

a) ☐ (Select to count service or compensation with a Predecessor Employer that *did not* maintain this Plan.) A Predecessor Employer that did not maintain this Plan is deemed to be the Employer for purposes of determining: (Select at least one.)

i) ☐ Entry Service

NOTE: The Entry Date for an employee of such Predecessor Employer shall be the earliest Entry Date on or after he has both met the entry requirements and is an Eligible Employee.

ii) ☐ Vesting Service

iii) ☐ Hours of Service required to be eligible for an Employer Contribution

iv) ☐ Compensation

Plan ID No. _____

NOTE: The crediting of such compensation shall be determined on a reasonably uniform basis for all similarly situated Employees based on all relevant facts and circumstances so as not to discriminate in favor of Highly Compensated Employees.

- b) Service with and compensation from such Predecessor Employer shall only be counted if service continued without interruption, unless otherwise specified in (i) below.
- i) ☐ Service and compensation is counted even if service did not continue without interruption.
- c) ☐ (Select if not counted for all such Predecessor Employers.) Service with or compensation from such Predecessor Employer shall be counted only as to a Predecessor Employer that (Select (i), (ii), or both.)
- i) ☐ maintained a qualified pension or profit sharing plan (or)
- ii) ☐ is named below: (Exact Legal Name(s).)

- 2) A PRIOR EMPLOYER is an Employee's last employer immediately prior to the Employer which is not a Predecessor Employer or a Controlled Group member, but for which service credit is granted under the Plan. Service with such Prior Employer shall be counted only if service continued without interruption.

- a) ☐ (Select to count service with a Prior Employer.) The following are Prior Employers for which service credit is granted under the Plan: (Exact legal name(s).)

- b) Service with such Prior Employer shall be counted for purposes of determining: (If (a) above is selected, select (i), (ii), or both.)

- i) ☐ Entry Service

NOTE: The Entry Date for an employee of such Prior Employer shall be the earliest Entry Date on or after he has both met the entry requirements and is an Eligible Employee.

- ii) ☐ Vesting Service

J. ELIGIBLE EMPLOYEE.

An Eligible Employee is any Employee of the Employer or of an Adopting Employer (See Item Z.) who is not excluded in (1) or (2) below. Notwithstanding any other provision of this Adoption Agreement or the Basic Plan Document, all employees of WCH, who continue in employment with the Employer on the Effective Date and who have participant accounts under the Plan shall automatically continue their participation in the Plan. Notwithstanding any other provision in this Adoption Agreement, other than

Plan ID No. _____

the provision below regarding the exclusion of per diem Employees, or Basic Plan Document, all employees who are Nurse Supervisors or Pharmacists shall be Eligible Employees.

An independent contractor is not an Employee. If the Internal Revenue Service (or another agency or court) determines that an individual who the Employer considered to be an independent contractor is an Employee, such individual shall become an Eligible Employee as soon as administratively feasible following the reclassification date, unless he is otherwise excluded in this item.

1) ☒ STATUTORY EXCLUSIONS. An Employee will not be an Eligible Employee if he is one of the following: *(These exclusions do not affect coverage testing. Select at least one.)*

a) ☐ BARGAINING EMPLOYEE. An Employee included in a unit of Employees covered by any collective bargaining agreement between the Employer and employee representatives, if retirement benefits were the subject of good faith bargaining and if two percent or less of the Employees who are covered pursuant to that agreement are professionals as defined in section 1.410(b)-9 of the regulations. For this purpose, the term "employee representatives" does not include any organization more than half of whose members are Employees who are owners, officers, or executives of the Employer.

b) ☒ NONRESIDENT ALIEN WITH NO U.S. INCOME. An Employee who is a nonresident alien, within the meaning of Code Section 7701(b)(1)(B), who receives no earned income, within the meaning of Code Section 911(d)(2), from the Employer that constitutes income from sources within the United States, within the meaning of Code Section 861(a)(3), or who receives such earned income but it is all exempt from income tax in the United States under the terms of an income tax convention.

2) ☒ NONSTATUTORY EXCLUSIONS. An Employee will not be an Eligible Employee if he is any of the following: *(Select at least one. Selections may affect testing done to determine if the minimum coverage requirement of Code Section 410(b) is met, unless otherwise indicated.)*

a) ☐ Employed in one of the employment classifications selected below. *(Select at least one.)*

i) ☐ Paid on a salaried basis

ii) ☐ Paid on a commission basis

iii) ☐ Paid on an hourly basis

b) ☐ Represented for collective bargaining purposes by the specific bargaining unit(s) named below:

(This exclusion does not affect coverage testing if requirements in (1)(a) above are met.)

c) ☐ A Leased Employee.

d) ☒ *(Select if continuing to exclude independent contractors who are reclassified as Employees.)* An individual considered by the Employer to be an independent contractor who is later determined by the Internal Revenue Service (or another agency or court) to be an Employee. Such individual shall continue to be excluded following the reclassification date.

Plan ID No. _____

e) ☐ A part-time, temporary, or seasonal Employee. A part-time, temporary, or seasonal Employee is an Employee who is regularly scheduled to work less than 1,000 Hours of Service in an Entry Service Period. In the event such an Employee (i) works at least 1,000 Hours of Service during an Entry Service Period based on the Hours of Service credited at the end of the Entry Service Period or (ii) his employment status changes to full-time, he shall become an Eligible Employee, unless he is otherwise excluded in this item.

f) ☐ Covered under any other qualified (Select (i), (ii), or both.)

i) ☐ profit sharing plan (or)

ii) ☐ pension plan

to which the Employer contributes.

NOTE: The exclusions entered in (g) and (h) below cannot be structured to result in the group of Nonhighly Compensated Employees participating in the Plan being only those Nonhighly Compensated Employees with the lowest amount of Compensation and/or the shortest service and who represent the minimum number of these Employees necessary to satisfy the minimum coverage requirement of Code Section 410(b).

g) ☐ Employed at one of the following locations(s) or division(s):

h) ☒ Employed in one of the following positions(s) or classification(s): (Cannot use an exclusion classification that indirectly imposes an impermissible age or service requirement.)

- Employees designated as per diem Employees;
- Employees who are covered by the Service and Maintenance Unit collective bargaining agreement by the Employer and SEIU United Healthcare Workers-West;
- An Employee who is a Highly Compensated Employee of the Employer with respect to the Plan Year, and who is not a collectively bargained employee covered by a collective bargaining agreement;
- An Employee designated in a position of manager or above, and who is not a collectively bargained Employee covered by a collectively bargaining agreement.

K. ENTRY REQUIREMENTS AND ENTRY DATE

An Employee is eligible to participate in the Plan in accordance with the provisions specified below. (Select at least one item for each grouping (service required and service method, age required, and Entry Date). Complete any applicable blanks for items selected. If the hours method for calculating Entry Service is selected in (1) below, (3)(b) below may be used to modify how service is determined. All service selections in the table below are made in the context of Entry Service in (3) below. Select (4) below if waiving age or service requirements for the Employer named in Item B.)

NOTE: If the Plan permits Rollover Contributions in Item R(2), an Eligible Employee can make Rollover Contributions to the Plan without satisfying the entry requirements. See Plan Section 3.04. The vesting must be 100% if over one year is used or if over 6 months and Entry Date is Yearly Date.

Plan ID No. _____

1) ENTRY REQUIREMENTS

Entry Requirements	All Contributions
Age Required	
No age	<input checked="" type="checkbox"/>
Age _____ (up to 21)	<input type="checkbox"/>
Service Required and Service Method	
No Service	<input type="checkbox"/>
1 year (elapsed time)	<input type="checkbox"/>
2 years (elapsed time)	<input type="checkbox"/>
1 year (hours)	<input type="checkbox"/>
2 years (hours)	<input type="checkbox"/>
12 months (up to 24, elapsed time)	<input checked="" type="checkbox"/>
_____ days a9up to 120, elapsed time)	<input type="checkbox"/>

2) ENTRY DATE

Entry Date	All Contributions
Day the entry requirements are satisfied	<input checked="" type="checkbox"/>
Monthly Date	<input type="checkbox"/>
Quarterly Date	<input type="checkbox"/>
Semi-yearly Date	
Yearly Date (age and service required cannot be over 20 ½ and 18 months, respectively)	<input type="checkbox"/>

3) ENTRY SERVICE. Subject to the provisions of Plan Section 1.02, Entry Service shall be determined based on the selection(s) made above and in (b) below, if applicable:

- a) ELAPSED TIME METHOD. Entry Service is the total of an Employee's Periods of Service without regard to Hours of Service.
- b) HOURS METHOD. A year of Entry Service is an Entry Service Period in which an Employee has at least 1,000 Hours of Service, unless otherwise specified in (i) below.
 - i) ☐ _____ (Up to 999.) Hours of Service.

Plan ID No. _____

- ii) CREDITING DATE. A year of Entry Service shall be credited at the end of the Entry Service Period, unless otherwise specified in A below.

A. ☐ A year of Entry Service shall be credited when the Employee has reached the specified number of Hours of Service during the Entry Service Period.

- iii) ENTRY SERVICE PERIOD is the consecutive 12-month period beginning on an Employee's Hire Date and the consecutive 12-month period ending on the last day of each following Plan Year, unless otherwise specified in A below. Following Plan Years shall include all Plan Years that begin after his Hire Date. (See Plan Section 1.02 for the crediting of Entry Service during the first two periods.)

A. ☐ An Entry Service Period is the consecutive 12-month period beginning on an Employee's Hire Date and each following consecutive 12-month period beginning on an anniversary of that Hire Date.

NOTE: The Entry Service Period for a rehired Employee who terminated employment prior to satisfying the entry requirements is based on his original Hire Date. If the Entry Service Period shifts to the Plan Year and such Employee is rehired after the first anniversary of his original Hire Date, his Entry Service Period shall be the Plan Year.

- 4) ☐ WAIVING ENTRY REQUIREMENTS. The requirements selected below shall be waived on _____, _____. (Month, day and year.) This date shall be an Entry Date if the Eligible Employee has met all the other entry requirements.

NOTE: This waiver applies only (i) to the Employer named in Item B and (ii) on the date filled in. Must be the Effective Date or later. See Item Z for the waiver of entry requirements for an Adopting Employer.

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

L. HIGHLY COMPENSATED EMPLOYEE AND TESTING METHODS (NOT APPLICABLE)

- 1) HIGHLY COMPENSATED EMPLOYEE. The definition of Highly Compensated Employee in Plan Section 1.02 is modified below. (Select any that apply.)

a) ☐ TOP-PAID GROUP ELECTION. (Select to limit the number of Highly Compensated Employees to the top 20% of employees based on compensation (top-paid group).) In determining who is a Highly Compensated Employee, the Employer makes a top-paid group election. The effect of this election is that an Employee (who is not a 5-percent owner at any time during the determination year or the look-back year) with compensation in excess of \$120,000 (as adjusted) for the look-back year is a Highly Compensated Employee only if the Employee was in the top-paid group for the look-back year.

(b) ☐ CALENDAR YEAR DATA ELECTION. (Select to change the look-back year for compensation determination. This election has no effect if the Plan Year begins on January 1.) In determining who is a Highly Compensated Employee (other than as a 5-percent owner), the Employer makes a calendar year data election. The effect of this election is that the look-back year is the calendar year beginning with or within the look-back year.

Plan ID No. _____

NOTE: These elections must apply consistently to the determination years of all plans of the Employer except as provided in the definition of Highly Compensated Employee in Plan Section 1.02.

- 2) ~~TESTING METHODS. (Only applicable if the Plan provides for Matching Contributions or Participant Contributions.) This Plan shall use the prior year testing method for purposes of the ACP Test, unless otherwise specified in (a) below.~~

a) ~~☐ This Plan shall use the current year testing method for purposes of the ACP Test.~~

~~NOTE: The testing method cannot be changed from the current year testing method to the prior year testing method for a Plan Year unless (i) the Plan has been using the current year testing method for the preceding five Plan Years or, if less, the number of Plan Years the Plan has been in existence or (ii) if, as a result of a merger or acquisition described in Code Section 410(b)(6)(C)(i), the Employer maintains both a plan using the prior year testing method and a plan using the current year testing method and the change is made within the transition period described in Code Section 410(b)(6)(C)(ii).~~

b) ~~☐ If this is not a successor plan and the Plan is using the prior year testing method, for the first Plan Year this Plan permits any Participant to make Participant Contributions, provides for Matching Contributions, or both, the prior year's Nonhighly Compensated Employees' ACP, as defined in Plan Section 3.08, shall be three percent, unless otherwise specified in (i) below.~~

i) ~~☐ (Cannot be used with (a) above.) The Plan Year's ACP, as defined in Plan Section 3.08, shall be used for the Nonhighly Compensated Employees' ACP.~~

M. COMPENSATION.

NOTE: Compensation, as defined in Plan Section 1.02, is used for contribution determinations other than for top-heavy minimum contributions. Compensation, as defined in Plan Section 3.07, for the Limitation Year is used to determine the limit on Annual Additions. Compensation, as defined in Plan Section 3.07, for the Plan Year is used to determine the amount of top-heavy minimum contributions.

- 1) Compensation, as defined in Plan Sections 1.02 and 3.07, subject to any modifications set forth in this Item M means the definition under Information Required to be Reported Under Code Sections 6041, 6051, and 6052 ("Wages, Tips and Other Compensation" box on Form W-2) shall apply, unless otherwise specified in (a) or (b) below.

a) ☐ The definition under Code Section 3401(a) Wages shall apply.

b) ☒ The definition under Simplified 415 Compensation shall apply. Simplified 415 Compensation excludes amounts received from a nonqualified unfunded deferred compensation plan, unless otherwise specified in (i) below.

i) ☐ Amounts received from a nonqualified unfunded deferred compensation plan are included, to the extent includible in gross income.

- 2) POST-SEVERANCE COMPENSATION. Post-severance Compensation shall exclude (i) payments for unused accrued bona fide sick, vacation or other leave that the Employee would have been able to use if employment had continued; (ii) payments received by the Employee pursuant to a nonqualified unfunded deferred compensation plan and would have been paid at the same time if employment had continued; and (iii) salary continuation payments made for a Participant who is permanently and totally disabled, as defined in Code Section 22(e)(3), unless otherwise specified in (a) below.

Plan ID No. _____

a) ☒ Post-severance Compensation shall include *(Select at least one.)*

i) ☒ Such payments for unused accrued bona fide sick, vacation or other leave.

ii) ☐ Such payments received pursuant to a nonqualified unfunded deferred compensation plan, but only to the extent includible in gross income.

iii) ☐ Such salary continuation payments *(Select A or B.)*

A. ☐ for all Participants who are permanently and totally disabled for a fixed or determinable period.

B. ☐ only for Participants who were Nonhighly Compensated Employees immediately before becoming disabled.

3) ☒ CODE SECTION 414(s) SAFE HARBOR EXCLUSIONS. Compensation, as defined in Plan Section 1.02, shall exclude reimbursements or other expense allowances, fringe benefits (cash and noncash), moving expenses, deferred compensation (other than elective contributions), and welfare benefits.

4) ANNUAL COMPENSATION for an Allocation Year is an Employee's Compensation for the Compensation Year ending with or within the consecutive 12-month period ending on the last day of the Allocation Year. In no event will Annual Compensation exceed the Code Section 401(a)(17) compensation limit. *(Annual Compensation is used for the allocation of Discretionary Contributions.)*

The COMPENSATION YEAR is the consecutive 12-month period ending on the last day of each Allocation Year, unless otherwise specified in (a) below.

a) ☐ *(Only available if the WAVE and comparability allocation formulas are not selected in Items N(1)(c) and (d).)* The Compensation Year is the consecutive 12-month period ending on each _____, _____. *(Month and day.)* If the Allocation Year is not the Plan Year, the Compensation Year for an Employee whose Hire Date is less than 12 months before the end of the consecutive 12-month period designated, Compensation shall be determined over the consecutive 12-month period ending on the last day of the Plan Year.

If (i) the Allocation Year is the Fiscal Year, (ii) the Fiscal Year is a 52-53 week period, and (iii) (a) above is not selected, then the Compensation Year shall be such 52-53 week period.

ANNUAL COMPENSATION MODIFICATIONS: *(Select any that apply.)*

b) ☒ Annual Compensation shall not include Compensation over Section 401(a)(17) limit. *(Up to the Code Section 401(a)(17) compensation limit.)*

c) ☒ *(Cannot use with (a) above.)* Annual Compensation shall exclude Compensation for the portion of the Compensation Year in which an Employee is not an Active Participant.

NOTE: Excluding Compensation while not an Active Participant may result in additional Contributions needed to satisfy the top-heavy requirements, described in Plan Section 11.04, during any Plan Year in which this Plan is a Top-heavy Plan.

5) ☐ In addition to the Code Section 414(s) safe harbor exclusions in (3) above, if applicable, Compensation for purposes of determining the allocation or amount of Contributions excludes: *(Exclusions are not permitted if integrated allocation formula is used. Select at least one.)*

a) ☐ bonuses

Plan ID No. _____

- b) ☐ commissions
- c) ☐ overtime
- d) ☐ other special compensation: *(Specify type of compensation excluded.)* _____

NOTE: Exclusions for purposes of Discretionary Contributions will require Code Section 414(s) nondiscrimination testing.

N. EMPLOYER CONTRIBUTIONS AND FORFEITURES. (Select (1), (2), or both.)

- 1) ☒ **DISCRETIONARY CONTRIBUTIONS.** *(If (2) below is not selected, Employer Contributions shall be substituted for Discretionary Contributions wherever it appears in this Adoption Agreement.)* Discretionary Contributions may be made for each payroll period in an amount determined by the Employer. Discretionary Contributions shall be allocated as of each payroll period to all Eligible Employees, except for the following:

- Employees designated as per diem Employees;
- Employees less than .5 FTE;
- Employees who are covered by the Service and Maintenance Unit collective bargaining agreement by the Employer and SEIU United Healthcare Workers-West;
- An Employee who is employed in a position other than as a pharmacist, who has been a Highly Compensated Employee of the Employer with respect to each Plan Year, and who is not a collectively bargained employee covered by a collective bargaining agreement;
- An Employee who is employed as a pharmacist, who is a Highly Compensated Employee of the Employer with respect to each Plan Year, and who is not a collectively bargained employee covered by a collective bargaining agreement;
- An Employee designated in a position of manager or above.

The amount allocated shall be equal to the amount determined in (a), (b), (c), or (d) below. *(Select (a), (b), (c), or (d).)*

NOTE: The allocation formulas in (a) and (b) below are design-based safe harbors under Code Section 401(a)(4), unless selections are made in Item M or O that are specifically identified as requiring nondiscrimination testing.

- a) ☒ **COMPENSATION FORMULA.** Discretionary Contributions shall be allocated using Compensation for the current payroll period. The amount allocated shall be equal to the Discretionary Contributions multiplied by the ratio of such person's payroll period Compensation to the total payroll period Compensation for all such persons.

- b) ☐ ~~**INTEGRATED FORMULA.** *(Only available if Adopting Employers Separate Plans are not selected in Item Z.)*~~

- i) ~~**PROVIDE TOP HEAVY MINIMUM CONTRIBUTION.** Discretionary Contributions shall be allocated to provide the top-heavy minimum contribution under Plan Section 11.04, unless otherwise specified in A below.~~

Plan ID No. _____

Subject to the overall permitted disparity limits, Discretionary Contributions shall be allocated using Annual Compensation for the Allocation Year as follows:

~~STEP ONE: This step one shall only apply in years in which the Plan is a Top-heavy Plan, as defined in Plan Section 11.02, and the minimum contribution under Plan Section 11.04 is not being provided by other contributions to this Plan or another plan of the Employer.~~

~~The allocation in this step one shall be made to each person meeting the requirements in Item O and each person who is entitled to a minimum contribution under Plan Section 11.04. Each such person's allocation shall be an amount equal to the Discretionary Contributions multiplied by the ratio of such person's Annual Compensation to the total Annual Compensation of all such persons. Such amount shall not exceed 3% of such person's Annual Compensation. The allocation for any person who does not meet the requirements in Item O shall be limited to the amount necessary to fund the minimum contribution.~~

~~STEP TWO: This step two shall only apply in years in which step one applies. The allocation in this step two shall be made to each person meeting the requirements in Item O. Each such person's allocation shall be equal to any amount remaining after the allocation in step one multiplied by the ratio of such person's Annual Compensation over the Integration Level to the total Annual Compensation over the Integration Level of all such persons. Such amount shall not exceed 3% of such person's Annual Compensation over the Integration Level.~~

~~For purposes of this step two, in the case of any person who has exceeded the cumulative permitted disparity limit described below, such person's total Annual Compensation shall be taken into account and the applicable allocation limit for such person shall be 3% of such person's total Annual Compensation.~~

~~STEP THREE: The allocation in this step three shall be made to each person meeting the requirements in Item O. Each such person's allocation shall be equal to any amount remaining after the allocation in step two multiplied by the ratio of the sum of such person's total Annual Compensation and his Annual Compensation over the Integration Level to the total of such sums for all such persons. Such amount shall not exceed an amount equal to a percentage (equal to the Maximum Integration Rate) of the sum of such person's total Annual Compensation and his Annual Compensation over the Integration Level.~~

~~If steps one and two apply, the Maximum Integration Rate minus 3% shall be substituted for the Maximum Integration Rate wherever it appears in this step three.~~

~~For purposes of this step three, in the case of any person who has exceeded the cumulative permitted disparity limit described below, two times such person's total Annual Compensation shall be taken into account and the applicable allocation limit for such person shall be a percentage (equal to the Maximum Integration Rate) of two times such person's total Annual Compensation.~~

~~STEP FOUR: The allocation in this step four shall be made to each person meeting the requirements in Item O. Each such person's allocation shall be equal to any amount remaining after the allocation in step three multiplied by the ratio of such person's Annual Compensation to the total Annual Compensation of all such persons.~~

~~A. ☐ DO NOT PROVIDE TOP HEAVY MINIMUM CONTRIBUTION. Subject to the overall permitted disparity limits, Discretionary Contributions shall be allocated using Annual Compensation for the Allocation Year to each person meeting the requirements in Item O. Each such person's allocation shall be determined as follows:~~

Plan ID No. _____

~~STEP ONE: An amount equal to the Discretionary Contributions multiplied by the ratio of the sum of such person's total Annual Compensation and his Annual Compensation over the Integration Level to the total of such sums for all such persons. Such amount shall not exceed an amount equal to a percentage (equal to the Maximum Integration Rate) of the sum of such person's total Annual Compensation and his Annual Compensation over the Integration Level.~~

~~For purposes of this step one, in the case of any person who has exceeded the cumulative permitted disparity limit described below, two times such person's total Annual Compensation shall be taken into account and the applicable allocation limit for such person shall be a percentage (equal to the Maximum Integration Rate) of two times such person's total Annual Compensation.~~

~~STEP TWO: Any amount remaining after the allocation in step one multiplied by the ratio of such person's Annual Compensation to the total Annual Compensation of all such persons.~~

The INTEGRATION LEVEL is the Taxable Wage Base as in effect on the latest Yearly Date, unless otherwise specified in (ii) or (iii) below.

ii) ☐ \$ _____. (Must be less than such Taxable Wage Base.)

iii) ☐ _____ % of such Taxable Wage Base. (Must be more than 19% and less than 100%.)

The MAXIMUM INTEGRATION RATE shall be determined according to the following schedule:

INTEGRATION LEVEL	MAXIMUM INTEGRATION RATE
100% of TWB	5.7%
Less than 100% but more than 80% of TWB	5.4%
More than 20% of TWB but not more than 80% of TWB	4.3%
Not more than 20% of TWB	5.7%

"TWB" means the Taxable Wage Base as in effect on the latest Yearly Date.

On any date the portion of the rate of tax under Code Section 3111(a) (in effect on the latest Yearly Date) that is attributable to old age insurance exceeds 5.7%, such rate shall be substituted for 5.7%. 5.4% and 4.3% shall be increased proportionately.

OVERALL PERMITTED DISPARITY LIMITS:

~~ANNUAL OVERALL PERMITTED DISPARITY LIMIT: Notwithstanding the preceding paragraphs, for any Plan Year any person eligible for an allocation under this formula benefits under another qualified plan or simplified employee pension, as defined in Code Section 408(k), maintained by the Employer or any other employer required to be aggregated with the Employer under Code Sections 414(b), (c), (m), or (o) that provides for permitted disparity (or imputes disparity),~~

Plan ID No. _____

~~Discretionary Contributions shall be allocated using (i) only step one, if applicable, and step four under (b)(i) if providing top-heavy minimum contribution and (ii) only step two under (b)(i)A if not providing top-heavy minimum contribution.~~

~~CUMULATIVE PERMITTED DISPARITY LIMIT: The cumulative permitted disparity limit for a person is 35 total cumulative permitted disparity years. Total cumulative permitted disparity years means the number of years credited to the person for allocation or accrual purposes under this Plan, any other qualified plan or simplified employee pension plan (whether or not terminated) ever maintained by the Employer or any other employer required to be aggregated with the Employer under Code Sections 414(b), (c), (m), or (o). For purposes of determining the person's cumulative permitted disparity limit, all years ending in the same calendar year are treated as the same year. If the person has not benefited under a defined benefit or target benefit plan maintained for any year beginning on or after January 1, 1994, the person has no cumulative permitted disparity limit.~~

~~NOTE: The allocation formulas in (c) and (d) below do not meet the safe harbor requirements of Code Section 401(a)(4).~~

- e) ☐ ~~AGE WEIGHTED (WAVE), PROVIDE TOP-HEAVY MINIMUM CONTRIBUTION. Discretionary Contributions shall be allocated to provide the top-heavy minimum contribution under Plan Section 11.04.~~

~~Discretionary Contributions shall be allocated using Benefit Factors for the Allocation Year. In years in which the Plan is a Top-heavy Plan, as defined in Plan Section 11.02, and the minimum contribution under Plan Section 11.04 is not being provided by other contributions to this Plan or another plan of the Employer, the allocation shall be made to each person meeting the requirements in Item O and each person entitled to a minimum contribution under Plan Section 11.04. In all other years the allocation shall be made to each person meeting the requirements in Item O. Each such person's allocation shall be an amount equal to Discretionary Contributions multiplied by the ratio of such person's Benefit Factor to the total Benefit Factors for all such persons. The allocation for any person who does not meet the requirements in Item O shall be limited to the amount necessary to fund the minimum contribution.~~

~~In years in which the Plan is a Top-heavy Plan, as defined in Plan Section 11.02, the minimum contribution under Plan Section 11.04 is not being provided by other contributions to this Plan or another plan of the Employer, and the allocation described above (or any subsequent allocation described below) would provide an allocation for any person less than the minimum contribution required for such person in Plan Section 11.04, such minimum contribution shall first be allocated to all such persons. Then any amount remaining shall be allocated to the remaining persons sharing in the allocation based on Benefit Factors as described above, as if they were the only persons sharing in the allocation for the Allocation Year.~~

~~8.5% INTEREST. The actuarial factor used to determine a person's Benefit Factor shall be the actuarial factor for the Allocation Year determined in Appendix A (based on an interest rate assumption of 8.5% and the mortality assumptions in the UP-1984 Table), unless a different appendix is specified in (i) or (ii) below.~~

- i) ☐ ~~7.5% INTEREST. Appendix B (based on an interest rate assumption of 7.5% and the mortality assumptions in the UP-1984 Table).~~
- ii) ☐ ~~8.0% INTEREST. Appendix C (based on an interest rate assumption of 8.0% and the mortality assumptions in the UP-1984 Table).~~

~~The allocation above meets the requirements in section 1.401(a)(4)-8(b)(1)(i)(B)(2) of the regulations, therefore a minimum gateway contribution is not required.~~

Plan ID No. _____

- d) ~~□ PARTICIPANT GROUP ALLOCATION (COMPARABILITY), PROVIDE TOP HEAVY MINIMUM CONTRIBUTION.~~ The Employer shall notify the Plan Administrator in writing, by the due date of the Employer's tax return for the year to which the Discretionary Contribution relates, the portion of such Contribution to be allocated to each Allocation Group. Discretionary Contributions determined for an Allocation Group shall be allocated using Annual Compensation for the Allocation Year to each person in the Allocation Group meeting the requirements in Item O. Each such person's allocation shall be equal to the Discretionary Contribution determined for the Allocation Group multiplied by the ratio of such person's Annual Compensation to the total Annual Compensation of all such person's in the Allocation Group.

~~MINIMUM ALLOCATION GATEWAY.~~ If the Employer allocates a Discretionary Contribution for any Allocation Year, the Employer shall make an additional Employer Contribution for such Allocation Year for each person who is a Nonhighly Compensated Employee and who had Employer Contributions made for or allocated to him for such Allocation Year if the sum of all Employer Contributions for such Nonhighly Compensated Employee is less than a minimum. The additional Employer Contribution shall be equal to the amount needed, if any, to bring the sum of all Employer Contributions up to the minimum. The amount of the minimum shall be equal to either (i) 5% of his Compensation or (ii) 1/3 of the "highest percentage" of his Compensation. The same minimum shall apply to all such persons and the minimum that applies shall be the minimum resulting in the smallest total additional Employer Contributions.

~~For purposes of determining the 5% minimum, Compensation means Compensation, as defined in Plan Section 3.07, for the Allocation Year. For purposes of determining the 1/3 of the highest percentage minimum, the highest percentage shall be the highest percentage of Compensation at which Employer Contributions are made for or allocated to any Highly Compensated Employee. The highest percentage shall be determined by dividing the Employer Contributions made for or allocated to each Highly Compensated Employee during the Allocation Year by the amount of his Compensation and selecting the greatest quotient (expressed as a percentage). For purposes of determining the 1/3 of the highest percentage minimum, including the determination of the highest percentage, Compensation means Annual Compensation for purposes of allocating Discretionary Contributions for the Allocation Year.~~

~~For purposes of determining the minimum allocation gateway, Employer Contributions shall not include Matching Contributions.~~

~~NOTE: In the case of a Self-employed Individual, the requirements of section 1.401(k)-1(a)(6) of the regulations continue to apply, and the allocation above shall not be such that a cash or deferred election is created for a Self-employed Individual.~~

~~This additional Employer Contribution shall be credited to the person's Account and shall be deemed to be a Discretionary Contribution.~~

~~ALLOCATION GROUPS.~~

~~NOTE: The criteria for determining the make-up of each Allocation Group cannot be subject to Employer discretion, which would cause the Plan to fail to have a definite allocation formula. The Allocation Groups cannot be structured to limit participation to only the shortest service and lowest paid Nonhighly Compensated Employees while excluding all other Nonhighly Compensated Employees.~~

~~The Allocation Groups shall be: (Complete (i) and (ii). Complete (iii) and (iv), if applicable. Four is the maximum number of Allocation Groups allowed on this Principal Financial Group Pre-approved Document for Profit Sharing Plans. Complete with titles or classifications.)~~

Plan ID No. _____

- i) ~~Group 1~~ _____
- ii) ~~Group 2~~ _____
- iii) ~~Group 3~~ _____
- iv) ~~Group 4~~ _____

2) ☐ MATCHING CONTRIBUTIONS. The Employer shall make Matching Contributions for each person meeting the requirements in Item O. (Select (a), (b), or both.)

a) ☐ MATCH REQUIRED OR OPTIONAL CONTRIBUTIONS. The amount of such Contributions shall be equal to the sum of (i) and (ii) below. (Select (i), (ii), or both.)

i) ☐ % of such person's Required Contributions made for the Allocation Year. (Item Q(1)(a) must be selected.)

ii) ☐ % of such person's Optional Contributions made for the Allocation Year. (Item Q(2) must be selected.)

NOTE: The selection of (b) below is only available if the Employer is a tax-exempt organization under Code Section 501(c)(3) and maintains a Code Section 403(b) plan separate and apart from this Plan. The election of this option does not establish a 403(b) plan for the Employer. No opinion is expressed as to whether a Code Section 403(b) plan that is maintained by the Employer, in addition to and separate from this Plan, satisfies the requirements of Code Section 403(b).

b) ☐ MATCH 403(b) PLAN ELECTIVE DEFERRAL CONTRIBUTIONS. The amount of such Contributions shall be calculated as of the last day of the Allocation Year using Elective Deferral Contributions and Compensation for the Allocation Year and shall be an amount equal to (Select (i) or (ii).)

i) ☐ STATED MATCH. % of such person's Elective Deferral Contributions to the Employer's 403(b) plan.

A. ☐ Elective Deferral Contributions that are over% of such person's Compensation won't be matched.

ii) ☐ STATED TIERED MATCH. (Complete A through D. For example: 100% of Elective Deferral Contributions that are not over 3% of Compensation, plus 50% of Elective Deferral Contributions that are over 3% but are not over 5% of Compensation.)

A. _____% of Elective Deferral Contributions that are not over _____% of Compensation, plus (First limit on Elective Deferral Contributions.)

B. _____% of Compensation, plus (First limit on Elective Deferral Contributions.)

C. _____% (Must be less than A.) of Elective Deferral Contributions that are over the percentage of Compensation specified in B but are not over

D. _____% (Must be more than B.) of Compensation. (Second limit on Elective Deferral Contributions.)

If Employer Contributions are made from Net Profits (Item O(1)(a) is selected) and Net Profits are not sufficient to provide Matching Contributions, such Contributions shall be proportionately reduced.

Plan ID No. _____

3) FORFEITURE APPLICATION.

Forfeitures of Nonvested Accounts when a Participant receives a distribution of his entire Vested Account, as described in Plan Section 3.05, shall occur as of the date the Participant receives, or is deemed to receive, the distribution, unless otherwise specified in (a) below.

- a) ☐ Such Forfeitures shall occur on the first day of the Plan Year following the Plan Year in which the Participant receives, or is deemed to receive, the distribution.

O. NET PROFITS AND CONTRIBUTION REQUIREMENTS.

- 1) Employer Contributions shall be made without regard to current or accumulated NET PROFITS, unless otherwise specified in (a) below.

- a) ☐ Employer Contributions shall be made out of current or accumulated Net Profits.

- 2) REQUIREMENTS FOR CONTRIBUTIONS. Employer Contributions and Forfeitures, if applicable, shall be made for or allocated to each person who was an Active Participant at any time during the Allocation Year, unless otherwise specified in (a), (b), (c), or (d) below.

NOTE: Selections may affect testing done to determine if the minimum coverage requirement of Code Section 410(b) is met, unless otherwise indicated.

- a) ☐ Such amounts shall be made for or allocated to each person who was an Active Participant at any time during the Allocation Year and either is an Active Participant on the last day of the Allocation Year or has more than 500 Hours of Service during the latest Accrual Service Period ending on or before the last day of the Allocation Year, unless a lesser number of Hours of Service is specified in (i) below. *(This selection does not affect coverage testing if the Allocation Year and the Accrual Service Period are the Plan Year.)*

- i) ☐ Has more than _____ (Up to 499.) Hours of Service.

- b) ☐ Such amounts shall be made for or allocated to each person who is an Active Participant on the last day of the Allocation Year.

- c) ☐ Such amounts shall be made for or allocated to each person who was an Active Participant at any time during the Allocation Year and has at least 1,000 Hours of Service during the latest Accrual Service Period ending on or before the last day of the Allocation Year, unless otherwise specified in (i) below.

- i) ☐ Has at least (Up to 999.) Hours of Service.

- d) ☐ Such amounts shall be made for or allocated to each person who is an Active Participant on the last day of the Allocation Year and has at least 1,000 Hours of Service during the latest Accrual Service Period ending on or before the last day of the Allocation Year, unless otherwise specified in (i) below.

- i) ☐ Has at least (Up to 999.) Hours of Service.

The requirements in (a), (b), (c), or (d) above are modified as follows:

- e) ☐ Such amounts shall also be made for or allocated to each person who was an Active Participant at any time during the Allocation Year and (i) dies or (ii) has a Severance from Employment after he reaches his Normal Retirement Date or becomes disabled. Such amounts shall also be made for or allocated to each person who was an Active Participant at any time

Plan ID No. _____

during the Allocation Year and has died or become disabled while performing Qualified Military Service during the Allocation Year. For purposes of this paragraph, disabled means the disability is subsequently determined to meet the definition of Totally Disabled.

3) The ALLOCATION YEAR is the Plan Year, unless otherwise specified in (a) below.

a) ☐ (Only available if Items N(1)(c), N(1)(d), and N(2) are not selected.) The Allocation Year is the Fiscal Year ending in the Plan Year.

NOTE: Selecting (a) above may affect testing done to determine if the minimum coverage requirement of Code Section 410(b) is met. Selecting (a) above will require nondiscrimination testing to determine if the nondiscrimination requirement of Code Section 401(a)(4) is met.

4) The ACCRUAL SERVICE PERIOD is the consecutive 12-month period ending on the last day of each Allocation Year.

P. CONTRIBUTION MODIFICATIONS.

CONTRIBUTION LIMITATIONS. The Annual Additions for a Participant during a Limitation Year shall not be more than the Maximum Annual Addition. (See Plan Section 3.07.)

1) The LIMITATION YEAR is the consecutive 12-month period ending on the last day of each Plan Year, unless otherwise specified in (a) below.

a) ☐ The Limitation Year is the consecutive 12-month period ending on each

_____. (Month and day.)

NOTE: The same limitation year must be used in all plans maintained by the Employer.

2) MULTIPLE DEFINED CONTRIBUTION PLANS. (This item applies if the Employer, as defined in Plan Section 1.02, or an Employer, as defined in Plan Section 3.07, maintain another qualified defined contribution plan that is not a Plan in which any Participant in this Plan is or was or could become a participant.) If the Participant is covered under another qualified defined contribution plan maintained by the Employer, as defined in Plan Section 3.07, the provisions of (c) through (e) of Plan Section 3.07 shall apply, unless otherwise specified in (a) below. (Plan Section 3.07 limits the last Annual Additions.)

a) ☐ The method described on the attached page(s) shall be used to limit total Annual Additions to the Maximum Annual Addition and shall properly reduce the excess amounts in a manner that precludes Employer discretion. (If selected, the Employer will provide the method for limiting Annual Additions on the attached page(s).)

~~TOP HEAVY PLAN REQUIREMENTS. The amount and allocation of Contributions shall be subject to the provisions of Article XI of the Basic Plan in Plan Years when this is a Top-heavy Plan, as defined in Plan Section 11.02. Special minimum contribution provisions will apply in such years.~~

~~3) ☐ MULTIPLE PLANS. (Use this item to specify which plan will provide the minimum contribution or benefit for participants who are covered under this Plan and any other plan or plans of the Employer. If selected, the Employer must provide wording on the attached page(s).) The method described on the attached page(s) shall be used to meet the minimum contribution and benefit requirements in Plan Years when this is a Top-heavy Plan, in a manner that precludes Employer discretion.~~

Plan ID No. _____

Q. REQUIRED CONTRIBUTIONS AND OPTIONAL CONTRIBUTIONS.

1) REQUIRED CONTRIBUTIONS. A Participant is not required to make Contributions in order to participate in the Plan, unless otherwise specified in (a) below.

a) ☐ (Must select if Item N(2)(a)(i) is selected.) A Participant is required to make Contributions in order to participate in the Plan. The amount of each Required Contribution made by an Active Participant

shall be _____ % of the Participant's Compensation for the payroll period.

2) ☐ OPTIONAL CONTRIBUTIONS. (Only available if Item N(2)(a)(ii) is selected. Must select if Item N(2)(a)(iii) is selected. If selected, the Plan is subject to an ACP Test.) A Participant is permitted to make Optional Contributions. The amount of Optional

Contributions for a payroll period may be any amount up to _____ % of the Participant's Compensation for the payroll period.

R. VOLUNTARY CONTRIBUTIONS AND ROLLOVER CONTRIBUTIONS.

1) VOLUNTARY CONTRIBUTIONS are not permitted, unless otherwise specified in (a) below.

a) ☐ Voluntary Contributions are permitted. (Select any that apply.)

i) ☐ _____ % of Compensation is the minimum Voluntary Contribution. (Must be more than 0% and less than 50%.)

ii) ☐ Voluntary Contributions must be a whole percentage of Compensation.

iii) ☐ % of Compensation is the maximum Voluntary Contribution. (Must be more than 0% and less than 100%.)

2) ROLLOVER CONTRIBUTIONS are permitted, unless otherwise specified in (a) below.

a) ☐ Rollover Contributions are not permitted.

S. INVESTMENTS.

1) The Plan does not have a Trust Agreement in effect, unless otherwise specified in (a) below.

a) ☒ TRUST AGREEMENT. The Plan has at least one Trust Agreement in effect.

2) INVESTMENT DIRECTION. Subject to the provisions of Article IV of the Basic Plan, the Annuity Contract, and if applicable, the Trust Agreement, the investment of a Participant's Account shall be directed by (Select one.)

a) ☒ the Participant for all Contributions.

b) ☐ the Employer for all Contributions.

c) ☐ the Participant for Participant Contributions and Rollover Contributions. The Employer for Employer Contributions.

Plan ID No. _____

3) LOANS. Loans to a Participant are not permitted, unless otherwise specified in (a) below.

a) ☒ (Only available if (1)(a) above is selected and the Trustee agrees to hold the promissory note.) Loans are available to a Participant subject to the provisions of Plan Section 5.06.

i) The Loan Administrator(s) is/are: (Fill in the person(s) or position(s) authorized to administer the Participant loan program. Neither Principal Life Insurance Company nor its affiliates can be named.)

Plan Administrator _____

ii) The minimum amount of any loan is \$1,000, unless otherwise specified in A or B below.

A. ☐ The minimum amount of any loan is \$_____. (Up to \$999)

B. ☐ No minimum loan amount applies.

iii) ☐ The maximum amount of any loan is the lesser of 50% of the Participant's Vested Account, reduced by any outstanding loan balance or \$_____ (Up to \$49,999), reduced by the highest outstanding loan balance during the one-year period ending on the day before the loan is made.

NOTE: If not selected, the maximum is the lesser of (i) 50% of the Participant's Vested Account, reduced by any outstanding loan balance or (ii) \$50,000, reduced by the highest outstanding loan balance during the one-year period ending on the day before the loan is made.

iv) ☐ SOURCE OF LOAN LIMITED. (Only available if Item Y(2)(a) is selected.) Loans shall only be available from the portion of the Participant's Vested Account resulting from all Contributions, excluding any amounts resulting from a direct or indirect transfer after December 31, 1984, of a defined benefit plan, money purchase plan, target benefit plan, stock bonus plan, or profit sharing plan that is subject to the survivor annuity requirements of Code Sections 401(a)(11) and 417.

NOTE: The Participant's Vested Account is used to determine the maximum amount of any loan. The amount a Participant may receive as a loan is limited to the Participant's Vested Account resulting from the Contributions selected above.

v) The number of outstanding loans for a Participant shall be limited to one, unless otherwise specified in A below.

A. ☒ The number shall be limited to 2. (Up to 5.)

vi) The number of loans approved for a Participant in a rolling 12-month period shall be limited to one, unless a different number or 12-month period is specified in A or B below.

A. ☒ The number shall be limited to 2. (Up to 5.)

B. ☒ The 12-month period shall be the (Select (1), (2), or (3).)

1) ☒ Plan Year.

2) ☐ calendar year.

Plan ID No. _____

3) ☐ deposit year as defined in the Annuity Contract.

vii) The term of the loan shall be limited to five years, unless otherwise specified in A below.

A. ☒ The term of the loan shall not be limited to five years for the purchase of a Participant's principal residence. Such loan term shall be limited to a period consistent with commercial home loan practices, unless otherwise specified in (1) below.

1) ☐ SPECIFIED LIMIT FOR PRINCIPAL RESIDENCE. The term of the loan shall be limited to the lesser of (i) 10 (Up to 25.) years or (ii) a period of years consistent with commercial home loan practices.

viii) TIMING OF A LOAN DEFAULT. If any payment of principal and interest, or any portion thereof, remains unpaid for more than 90 days after due, the loan shall be in default, unless otherwise specified in A or B below.

A. ☐ The loan shall be in default _____ (Up to 89.) days after due.

B. ☐ The loan shall be in default at the end of the calendar-year quarter following the calendar-year quarter in which the missed payment was due.

ix) SEVERANCE FROM EMPLOYMENT. An outstanding loan shall become due and payable in full 60 days after a Participant has a Severance from Employment and ceases to be a party-in-interest as defined in ERISA or after complete termination of the Plan.

However, subject to the provisions of Plan Section 5.06 and in accordance with nondiscriminatory procedures set up by the Loan Administrator, an outstanding loan balance shall not be due and payable at such time as modified in A or B below.

A. An outstanding loan shall not be due and payable at such time if a Participant impacted by a business event, as described in Plan Section 5.06, elects a Direct Rollover to another qualified plan that includes the loan note, unless otherwise specified in (1) or (2) below.

1) ☒ The ability to roll over an outstanding loan note shall not be limited to Participants impacted by a business event.

2) ☐ Rollovers of an outstanding loan note are not permitted.

B. ☐ A Participant may continue to repay an outstanding loan balance after Severance from Employment.

T. VESTING PERCENTAGE.

Vesting Percentage is used to determine the nonforfeitable percentage of a Participant's Account resulting from Employer Contributions.

The Vesting Percentage for a Participant who is an Employee on or after the date he reaches Normal Retirement Age or Early Retirement Age shall be 100%. The Vesting Percentage for a Participant who is an Employee on the date he dies or the date he becomes disabled shall be 100%. The Vesting Percentage shall also be 100% for a Participant who dies or becomes disabled while performing Qualified Military Service. For purposes of this paragraph, disabled means the disability is subsequently determined to meet the definition of Totally Disabled.

Plan ID No. _____

- 1) VESTING SCHEDULE. A Participant's Account resulting from Employer Contributions is subject to the vesting schedule selected below. (Select one. If (d) is selected, fill in percentages.)

VESTING SERVICE (whole years)	VESTING PERCENTAGE			
	(a)	(b)	(c)	(d)
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Less than 1	100	0	0	_____
1		0	0	_____
2		0	20	_____
3		100	40	_____
4			60	_____
5			80	_____
6 or more			100	_____

NOTE: The schedule in (d) must provide 100% vesting after 3 years of Vesting Service or must at all times be as great as the Vesting Percentage that the schedule in (c) would provide.

A Participant's Vesting Percentage determined above shall never be reduced in later years.

U. VESTING SERVICE

Vesting Service, subject to the provisions of Plan Section 1.02, shall be the total of an Employee's countable Periods of Service without regard to Hours of Service (elapsed time method), unless otherwise specified in (1) below.

- 1) ☐ HOURS METHOD. A year of Vesting Service is a Vesting Service Period in which an Employee has at least 1,000 Hours of Service, unless otherwise specified in (a) below.
- a) ☐ _____ (Up to 999) Hours of Service.
- b) A VESTING SERVICE PERIOD is the consecutive 12-month period ending on the last day of each Plan Year, unless otherwise specified in (i) below.
- i) ☐ The consecutive 12-month period ending on each _____.
(Month and day)
- c) A VESTING BREAK, when the hours method is used, is a Vesting Service Period in which an Employee is credited with not more than one-half of the Hours of Service required for a year of Vesting Service, unless otherwise specified in (i) below.
- i) ☐ _____ or fewer Hours of Service. (Fill in up to 500 hours but less than hours required for a year of Vesting Service)

NOTE: If the hours method is used, the date completed in (2) below should be the first day of Vesting Service Period. If the first day of such period is not used, service during the period in which the date occurs shall not be excluded because of that modification. If the hours method is used and (3) is selected, service during the period in which the Employee attains the age completed in (3) shall not be excluded because of that modification. If the Employer had a previous plan that terminated within five years of the Effective Date of this Plan, the Employer must treat the effective date of the terminated plan as the Effective Date of this Plan for purposes of the selection in (2) below.

Plan ID No. _____

VESTING SERVICE MODIFICATIONS:

- 2) ☐ Service before _____, _____ (Month, day and year)

NOTE: If selected, fill in a date on or before the date the Plan became subject to ERISA. A new plan becomes subject to ERISA on its Effective Date.

- 3) ☐ Service before an Employee attains age (Up to 18) shall not be counted.

- 4) ☐ (Select only if Participant Contributions are now or have been required for participation in the (Prior) Plan.) Service while an Eligible Employee does not make the Contributions required in order to be an Active Participant shall not be counted.

NOTE: If the hours method is used, service during a Vesting Service Period in which the Participant makes any Required Contributions shall not be excluded because of this item

V. EQUIVALENCIES.

Hours of Service shall be determined on the basis of actual Hours of Service that an Employee is paid or entitled to payment if the Employer maintains hourly records for such Employee. If the Employer does not maintain hourly records for an Employee, Hours of Service shall be determined on the basis of months worked and an Employee shall be credited with 190 Hours of Service for each month in which he would otherwise be credited with at least one Hour of Service, unless otherwise specified in (1), (2) or (3) below.

- 1) ☐ DAYS. On the basis of days worked. An Employee shall be credited with 10 Hours of Service for each day in which he would otherwise be credited with at least one Hour of Service.
- 2) ☐ WEEKS. On the basis of weeks worked. An Employee shall be credited with 45 Hours of Service for each week in which he would otherwise be credited with at least one Hour of Service.
- 3) ☐ ALL EMPLOYEES. The equivalency described above shall apply to all Employees.

W. WITHDRAWAL BENEFITS.

- 1) VOLUNTARY. A Participant may withdraw any part of his Vested Account resulting from Voluntary Contributions, unless such withdrawals are not permitted in (c) below.

A Participant may make two such withdrawals in any 12-month period, unless otherwise specified in (a), (b) or (c) below.

- a) ☐ A Participant may make such a withdrawal at any time.
- b) ☐ A Participant may make _____ such withdrawal(s) in any 12-month period.
- c) ☐ Withdrawal of Voluntary Contributions is not permitted.

- 2) ROLLOVER. A Participant may withdraw any part of his Vested Account resulting from Rollover Contributions, unless such withdrawals are not permitted in (c) below.

A Participant may make two such withdrawals in any 12-month period, unless otherwise specified in (a), (b), or (c) below.

- a) ☐ A Participant may make such a withdrawal at any time.

Plan ID No. _____

- b) ☐ A Participant may make _____ such withdrawal(s) in any 12-month period.
- c) ☒ Withdrawal of Rollover Contributions is not permitted.
- 3) ☒ **HARDSHIP.** A Participant may withdraw any part of his Vested Account resulting from Matching Contributions and Discretionary Contributions in the event of hardship due to financial need. The withdrawal is subject to the provisions of Plan Section 5.05.
- 4) ☐ **AGE 59 1/2.** A Participant may withdraw any part of his Vested Account resulting from Matching Contributions and Discretionary Contributions any time after he attains age 59 1/2.

A Participant may make two such withdrawals in any 12-month period, unless otherwise specified in (a) or (b) below.

- a) ☐ A Participant may make such a withdrawal at any time.
- b) ☐ A Participant may make _____ such withdrawal(s) in any 12-month period.
- 5) ☐ **FIVE YEARS AS AN ACTIVE PARTICIPANT.** A Participant may withdraw any part of his Vested Account resulting from Matching Contributions and Discretionary Contributions at any time after he has been an Active Participant for at least five years.

A Participant may make two such withdrawals in any 12-month period, unless otherwise specified in (a) or (b) below.

- a) ☐ A Participant may make such a withdrawal at any time.
- b) ☐ A Participant may make _____ such withdrawal(s) in any 12-month period.

NOTE: Withdrawals are subject to the distribution of benefits provisions of Article VI or VIA of the Basic Plan, whichever applies.

X. RETIREMENT AND THE START OF BENEFITS.

- 1) **NORMAL RETIREMENT AGE** is the age at which the Participant's Account becomes nonforfeitable if he is an Employee. A Participant's Normal Retirement Age is age 65, unless otherwise specified in (a) or (b) below.
- a) ☐ Age _____. *(At least 55 and no more than 64.)*
- b) ☐ *(Only available if the WAVE and comparability allocation formulas are not selected in Items N(1)(c) and (d).)* The older of age _____ *(At least 55 and no more than 65.)* or his age on the *(Select (i) or (ii).)*
- i) ☐ date _____ *(Up to 5.)* years after the first day of the Plan Year in which his Entry Date occurred.
- ii) ☐ earlier of the date *(Up to 5.)* years after his Hire Date or the date 5 years after the first day of the Plan Year in which his Entry Date occurred.

The provisions of (b) are modified as follows:

- c) ☐ A Participant's Normal Retirement Age shall not be older than age _____. *(At least the age in (b) and no more than 70.)*

Plan ID No. _____

NOTE: If the Plan includes monies from a money purchase plan or another direct or indirect transfer described in Item Y(3), and (a) or (b) is selected, the age entered cannot be less than 62.

- 2) NORMAL RETIREMENT DATE, DATE REACHES. Normal Retirement Date means the date a Participant reaches his Normal Retirement Age, unless otherwise specified in (a) below.
- a) ☐ FIRST OF MONTH ON OR AFTER. Normal Retirement Date means the earliest first day of the month on or after a Participant reaches his Normal Retirement Age.
- 3) START OF RETIREMENT BENEFITS. A Participant may choose to have retirement benefits begin before he has a Severance from Employment and on or after his Normal Retirement Date, unless otherwise specified in (a) below.
- a) ☐ A Participant may not choose to have retirement benefits begin before he has a Severance from Employment.
- 4) EARLY RETIREMENT DATE. (Select (a) or (b).)
- a) ☒ PERMITTED. If (2)(a) above is selected, Early Retirement Date is the first day of the month before a Participant's Normal Retirement Date that he selects for receiving a distribution of his Vested Account as an early retirement benefit. If (2)(a) above is not selected, Early Retirement Date is any day before a Participant's Normal Retirement Date that he selects for receiving a distribution of his Vested Account as an early retirement benefit. This day shall be on or after the date the Participant has a Severance from Employment and reaches Early Retirement Age. A Participant reaches Early Retirement Age on the date the following requirement(s) are met: (Select at least one. A Participant's Account is 100% vested if he is an Employee on or after he reaches this age.)
- i) ☒ He is age 55. (Less than age in (1) above.)
- ii) ☐ He has _____ (Up to 6) years of Vesting Service.
- iii) ☐ He is within _____. (Up to 6) years of Normal Retirement Date.
- iv) ☐ He has been an Active Participant _____ (Up to 6) years.
- b) ☐ Early retirement is not permitted.
- 5) TOTALLY DISABLED. The definition of Totally Disabled is tied to Social Security disability, unless otherwise specified in (a), (b), or (c) below. (NOT APPLICABLE)
- a) ☐ ~~Tied to the Employer's long-term disability plan.~~
- b) ☐ ~~Determined by a physician chosen by the Plan Administrator and the disability has lasted or can be expected to last for at least 12 months.~~
- c) ☐ ~~Determined by a physician chosen by the Plan Administrator and the disability has lasted for at least five months.~~

~~NOTE: The determination of disability shall be applied uniformly to all Participants and may not discriminate in favor of Highly Compensated Employees. If (b) or (c) is selected, any benefit provided to a Participant who is Totally Disabled is a "disability benefit" subject to the special disability claim procedures in Plan Section 9.05(b).~~

Plan ID No. _____

6) VESTED BENEFIT MODIFICATIONS. Plan Section 5.03 permits an Inactive Participant to elect to receive a distribution after he has a Severance from Employment. The ability to receive a distribution is modified as follows: (Select (a) or (b), if applicable.)

a) ☐ An Inactive Participant cannot elect to receive a distribution from that part of his Vested Account resulting from

i) ☐ Employer Contributions

ii) ☐ Required and Optional Contributions

before he becomes Totally Disabled (Retirement Date or death, if earlier). A small Vested Account, as defined in Plan Section 10.11, shall be paid earlier.

b) ☐ An Inactive Participant cannot elect to receive a distribution from that part of his Vested Account resulting from Employer Contributions before he has had a Severance from Employment for a period of time (Retirement Date or death, if earlier). Payment of a small Vested Account, as defined in Plan Section 10.11, shall also be delayed.

The period of time is (Select (i) or (ii).)

i) ☐ _____ month(s). (Up to 60.)

ii) ☐ _____ year(s). (Up to 5.)

Y. FORMS OF DISTRIBUTION FOR RETIREMENT BENEFITS.

NOTE: If this Plan is a direct or indirect transferee after December 31, 1984, of a defined benefit plan, money purchase plan, target benefit plan, stock bonus plan, or profit sharing plan that is subject to the survivor annuity requirements of Code Sections 401(a)(11) and 417, (1)(b) and (1)(c) below cannot be selected.

If the Plan later becomes a direct or indirect transferee of a defined benefit plan, money purchase plan, target benefit plan, stock bonus plan, or profit sharing plan that is subject to the survivor annuity requirements of Code Sections 401(a)(11) and 417, then the options available under the Plan shall be those specified in (1)(a) below and (1)(a)(i), if applicable and the selection of (1)(b) or (1)(c) below cannot be used. The Plan must be amended to reflect the selection of (1)(a) below and (1)(a)(i) below, if applicable.

1) The options available under the Plan shall be: (Select (a), (b), or (c).)

a) ☒ INCLUDE LIFE ANNUITIES. Those specified in Plan Section 6.02 other than the fixed period and fixed payment installments, unless otherwise specified in (i) below.

i) ☒ INSTALLMENTS. The fixed period and fixed payment installment options shall be available.

b) ☐ NO LIFE ANNUITIES. Those specified in subparagraph (a)(2) of Plan Section 6A.02 other than the fixed period and fixed payment installments, unless otherwise specified in (i) below.

i) ☐ INSTALLMENTS. The fixed period and fixed payment installment options shall be available.

Plan ID No. _____

- c) ☐ SINGLE SUM, PARTIAL PAYMENTS, AND DISTRIBUTIONS IN KIND. Those specified in subparagraph (a)(1) of Plan Section 6A.02 other than the fixed period and fixed payment installments, unless otherwise specified in (i) below.
- i) ☐ INSTALLMENTS. The fixed period and fixed payment installment options shall be available.
- 2) The Plan does not include monies from a money purchase plan or another direct or indirect transfer described in (3) below, unless otherwise specified in (a) below.
- a) ☒ Monies from a money purchase plan or another direct or indirect transfer are held under the Plan.
- 3) SPOUSAL CONSENT FOR DISTRIBUTIONS. If the Plan is not a direct or indirect transferee after December 31, 1984, of a defined benefit plan, money purchase plan, target benefit plan, stock bonus plan, or profit sharing plan that is subject to the survivor annuity requirements of Code Sections 401(a)(11) and (417), spousal consent is not required for electing an optional form of retirement benefit that is not a life annuity.
- If the Plan is such direct or indirect transferee, spousal consent shall be required for all Participants electing an optional form of retirement benefit that is not a life annuity, unless otherwise specified in (a) below.
- a) ☐ Spousal consent is required for distributions other than a life annuity if any portion of a Participant's Account resulted from such direct or indirect transfer regardless of whether or not the distribution includes the transferred assets, unless otherwise specified in (i) below.
- i) ☐ Spousal consent is only required if the distribution includes any transferred assets.

The spousal consent requirements above are modified as follows:

- b) ☒ Spousal consent shall be required for all distributions.

Z. ADOPTING EMPLOYERS. (Identify Adopting Employers below.)

NOTE: The Plan must meet the minimum coverage requirement of Code Section 410(b) taking into account all employees of Controlled Groups and Affiliated Service Groups. If the Employer is a member of such a group, other employers in the group may need to adopt this Plan in order for the Plan to meet this requirement. Some employers of the group may also choose to adopt this Plan even though not required. Use this item to identify the other employers in the group whose employees may become Participants.

- 1) There are no Adopting Employers, unless otherwise specified in (a) below.
- a) ☐ The Adopting Employers listed in (3) below participate with the Employer in a single plan or establish a separate plan for the benefit of their Employees, as specified.
- 2) Single Plan or Separate Plans
- a) SINGLE PLAN. Adopting Employers may participate with the Employer in a single plan. An Adopting Employer's agreement to participate in this Plan shall be evidenced in writing according to the provisions of Plan Section 2.04.

NOTE: The provisions of Plan Section 10.03 shall apply in the case of the merger of this Plan with any Prior Plan of an Adopting Employer participating with the Employer in a single plan.

Plan ID No. _____

- b) SEPARATE PLANS. Adopting Employers may establish a separate plan for the exclusive benefit of their Employees. The establishment of an Adopting Employer's separate plan shall be evidenced in writing according to the provisions of Plan Section 2.05.

NOTE: A separate plan should not be established unless (i) each plan can meet the minimum coverage requirement of Code Section 410(b) separately or (ii) the combined plans can meet the minimum coverage requirement of Code Section 410(b) and the nondiscrimination requirement of Code Section 401(a)(4). The combined plans may not meet the requirement of Code Section 401(a)(4) if the plans provide for a Discretionary Contribution that is determined separately for each Adopting Employer.

3) The Adopting Employers are:

NOTE: This Item must be completed with at least one Adopting Employer if (1) above is selected.

a) Name _____

Date of Adoption or Participation _____, _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____, _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____, _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

Plan ID No. _____

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

b) Name _____

Date of Adoption or Participation _____, _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____, _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____, _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

Plan ID No. _____

c) Name _____

Date of Adoption or Participation _____, _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____, _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____, _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

d) Name _____

Date of Adoption or Participation _____, _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____, _____
(Month, day and year.)

Plan ID No. _____

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____ , _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

e) Name _____

Date of Adoption or Participation _____ , _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____ , _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

Plan ID No. _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____ , _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

f) Name _____

Date of Adoption or Participation _____ , _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____ , _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

Plan ID No. _____

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____ , _____
(Month, day and year.)

iv) Complete A below, if applicable.

A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. (The selections in Item K(4) apply only to the Employer named in Item B.)

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

g) Name _____

Date of Adoption or Participation _____ , _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____ , _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____ , _____
(Month, day and year.)

Plan ID No. _____

iv) Complete A below, if applicable.

- A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. *(The selections in Item K(4) apply only to the Employer named in Item B.)*

Date _____
(Month, day and year)

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

h) Name _____

Date of Adoption or Participation _____, _____ (Month, day and year. Must be on or after the Plan's original effective date in Item D.)

Executed _____, _____
(Month, day and year.)

By _____
(Signature)

Business Title _____

i) Single Plan or Separate Plans

☐ Single Plan ☐ Separate Plans

ii) Complete A, B, and C below if Separate Plans.

A. EIN _____

B. Plan No. _____ (3-digit number used for Form 5500 reporting.)

C. Fiscal Year End _____
(Month, day and year)

iii) Complete A below if this Adopting Employer had a Prior Plan.

A. Date Prior Plan established _____, _____
(Month, day and year.)

iv) Complete A below, if applicable.

- A. This Adopting Employer has waived the entry requirements selected below for its Employees who are Eligible Employees on the date specified. *(The selections in Item K(4) apply only to the Employer named in Item B.)*

Date _____
(Month, day and year)

Plan ID No. _____

	All Contributions
Service requirement	<input type="checkbox"/>
Age requirement	<input type="checkbox"/>

AA. MERGER OR SPIN-OFF.

1) ☐ MERGER. The following plan(s) merged into this Plan:

a) Name _____

Effective date of merger _____ , _____
 (Month, day and year.)

b) Name _____

Effective date of merger _____ , _____

c) Name _____

Effective date of merger _____ , _____

d) Name _____

Effective date of merger _____ , _____

2) ☐ SPIN-OFF. This Plan was a restatement due to a spin-off from the following plan:

a) Name _____

Effective date of merger _____ , _____
 (Month, day and year.)

Plan ID No. _____

By executing this Adoption Agreement, the Employer, adopts the Plan for the exclusive benefit of its Employees. The selections and specifications contained in this Adoption Agreement and the terms, provisions, and conditions provided in the Basic Defined Contribution Document for the Watsonville Community Hospital 401(a) Plan constitute the Employer's PLAN. No other basic plan may be used with this Adoption Agreement.

It is understood that Principal Life Insurance Company is not a party to the Employer's Plan and shall not be responsible for any tax or legal aspects of the Employer's Plan. The Employer assumes responsibility for these matters. The Employer acknowledges that it has counseled, to the extent necessary, with selected legal and tax advisors. The obligations of Principal Life Insurance Company shall be governed solely by the provisions of its contracts and policies. Principal Life Insurance Company shall not be required to look into any action taken by the Plan Administrator, Named Fiduciary, Trustee, Investment Manager, or the Employer and shall be fully protected in taking, permitting, or omitting any action on the basis of the Employer's actions. Principal Life Insurance Company shall incur no liability or responsibility for carrying out actions as directed by the Plan Administrator, Named Fiduciary, Trustee, Investment Manager, or the Employer.

Note: The Employer must sign the Adoption Agreement when it first adopts the Plan; and must complete and sign a new Adoption Agreement if the Plan has been restated, or if the Plan has been amended to change any prior elections or make new elections.

(Complete in black ink.)

This Adoption Agreement is executed April 17, 2023.
(Date Signed. Month, day and year.)

FOR THE EMPLOYER

By my signature, I certify that I have reviewed the terms of and the Items selected within this Adoption Agreement. If the Plan has a Trust Agreement in effect, I hereby certify that a copy of this Plan document shall be provided to each Trustee.

By 
(Signature)

Print Name Allyson Hauck

Business Title Chief Human Resources Officer

Plan ID No. _____



Board Report

Meeting Date: April 26, 2023

Report Type: Discussion

Title: Update by Interim Chief Executive Officer (CEO)

Recommendation: Receive and file update from Matko Vranjes, Interim CEO

Contact: Matko Vranjes, Interim CEO

Analysis

At each board meeting the CEO provides the board and the public an oral update on various matters.

Financial Impact: None



Board Report

Meeting Date: April 26 ,2023

Report Type: Discussion

Title: Update by Chief Financial Officer (CFO)

Recommendation: Receive and file update from Julie Peterson, Chief Financial Officer

Contact: Julie Peterson, Chief Financial Officer

Analysis

At each board meeting the CFO provides the board and the public an update on Financial Performance.

Financial Impact: See delivered reports.

Attachment A: Financial Performance Reports-To Be Delivered



Board Report

Meeting Date: April 26, 2023

Report Type: Discussion

Title: Medical Committees Reports April 2023

Recommendation: Pass a **Motion** approving 1) the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of April 2023; and 2) the Medical Executive Committee (MEC) recommendation appointing Surgery Department Vice Chair – Sarah Brant, MD.

Contact: A Janelle Rasi, M.D., Vice Chief of Staff Chair, Medical Executive Committee

Analysis

At each board meeting the board receives reports from the Medical Executive Committee including the Credentials Report and the Interdisciplinary Practice Credentials Report.

Financial Impact: None.

Attachments:

A-Medical Executive Committee Report-To Be Delivered