PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

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

Closed Session Meeting Agenda

Wednesday, February 22, 2023-5:00 pm

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

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

Kathleen King Community Room - 85 Nielson Street, Watsonville

Pursuant to Pajaro Valley Health Care District Hospital Corporation (PVHCDHC) Resolutions adopted monthly, Assembly Bill 361, and guidance from the Santa Cruz County Health Department in response to concerns regarding COVID-19, Board Members of PVHCDHC are permitted to participate in this duly noticed public meeting via teleconference and certain requirements of The Brown Act are suspended.

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.orgpara solicitar interpretación.

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.

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 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. the day of the meeting and before the end of the meeting will be included with the minutes 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

Pajaro Valley Health Care District Hospital Corporation
Closed Session Agenda- Wednesday, February 22, 2023

Call to Order

Roll Call

Closed Session Public Comment

Closed Session

1. **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, COS

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.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Board Members

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

Regular Meeting Agenda

Wednesday, February 22, 2023-5:00 pm

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Pajaro Valley Health Care District Hospital Corporation
Regular Meeting Agenda- Wednesday, February 22, 2023

Call to Order

Roll Call

Closed Session Report

Agenda Modification Consideration

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 Board will be noted in the minutes and may be scheduled for discussion at a future meeting or referred to staff for clarification and report.

Comments from Board Members

Consent Agenda

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. **Assembly Bill 361 Approving the Use of Teleconference Meetings for Board of Directors**
   Recommendation: Pass a **Resolution** making findings and ordering the use of Teleconference Meetings of the Board of Directors due to Covid-19, pursuant to the requirements of Assembly Bill 361.
   Contact: Dawn Bullwinkel, Interim Clerk of the Board, dbullwinkel@watsonvillehospital.com

2. **Minute Approval: December 28, 2022 and January 25, 2023**
   Recommendation: Pass a **Motion** approving the minutes of the December 28, 2022 and January 25, 2023.
   Contact: Dawn Bullwinkel, Interim Clerk of the Board, dbullwinkel@watsonvillehospital.com

3. **Policies/Policy Summary Approval: February 2023**
   Recommendation: Pass a **Motion** approving the Policies/Policy Summary.
   Contact: Sherri Torres, Chief Nursing Officer, Sherri_StoutTorres@Watsonvillehospital.com

Information

4. **Chief Executive Officer Steven Salyer Oral Report on Operational Hospital Activities**
   Recommendation: Receive and file.
   Contact: Steven Salyer, Chief Executive Officer

Discussion Agenda

5. **Association of California Healthcare Districts (ACHD)**
   Recommendation: Receive and discuss ACHD presentation given by Cathy Martin, CEO and Sarah Bridge, Senior Legislative Advocate.
   Contact: Steven Salyer, Chief Executive Officer

6. **Medical Executive Committees Reports Report February 2023**
   Recommendation: Pass a **Motion** 1) approving Interdisciplinary Practice Credentials Report and 2) approving Medical Staff Items: a) Required current ACLS Certification for Hospitalists, add requirement to Privilege Lists, b) Updated OBGYN Privilege List and
   c) OBGYN OPPE/FPPE & Triggers.
   Contact: Clay Angel, M.D., Chief of Staff Chair, Medical Executive Committee

7. **Chief Financial Officer Monthly Financial Performance**
   Recommendation: Receive and file.
   Contact: Julie Peterson, Chief Financial Officer

Adjournment

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PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Consent

Title: AB 361-Resolution Authorizing Teleconference Meetings

Recommendation: Pass a Resolution authorizing making findings and ordering the use of teleconference meetings of the Board of Directors due to COVID-19, pursuant to the requirements of Assembly Bill 361; and Direct Staff to return within 30 days with a new resolution addressing the need to continue holding teleconference meetings consistent with the requirements of Assembly Bill 361.

Contact: Steven Salyer, Chief Executive Officer

Executive Summary

As a result of the continuing impacts of the COVID-19 pandemic, many local agencies have been holding teleconference meetings under the modified rules authorized under Assembly Bill 361. This item asks the Board to adopt a resolution ordering the use of teleconference meetings under the modified rules. This will allow Hospital Board members to appear at meetings remotely if they choose to do so.

Analysis

Many local legislative bodies have recognized that COVID-19 presents a continuing threat to the Santa Cruz County community and that there is an important governmental interest in protecting the health, safety, and welfare of those who participate in public meetings. Requiring all members of legislative bodies to appear in-person at meetings presents greater risk to the health and safety of meeting participants, including reduced social distancing among people of different communities, increased exposure for those who are immunocompromised or unvaccinated, and challenges associated with fully ascertaining and ensuring compliance with vaccination, face coverings, and other safety measures at such public meetings.

Pursuant to AB 361, a legislative body can hold teleconference meetings under the modified AB 361 teleconferencing rules if a state of emergency remains active, or local officials have recommended measures to promote social distancing, as long as the legislative body reconsiders the circumstances of the state of emergency and determines either that the state of emergency continues to directly impact the ability of the members to meet safely in person or that local officials continue to recommend measures to promote social distancing.

The Governor’s emergency proclamation has not been lifted and Dr. Newel’s social distancing recommendation remains in effect. The dangers presented by returning to non-emergency meeting protocols remain. Staff recommends that the Board adopt the draft resolution accompanying this item, which contains the findings necessary to hold teleconference meetings under the modified Brown Act rules.

Financial Impact: None

Attachments:

A. AB 361 Resolution

BEFORE THE BOARD OF DIRECTORS OF
THE PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION

RESOLUTION NO._

On the motion of Director
Duly seconded by Director

RESOLUTION AUTHORIZING TELECONFERENCE MEETINGS UNDER ASSEMBLY BILL 361 AS A RESULT OF THE CONTINUING COVID-19 PANDEMIC STATE OF EMERGENCY AND HEALTH OFFICER RECOMMENDATION FOR SOCIAL DISTANCING

WHEREAS, on March 4, 2020, Governor Newsom issued a Proclamation of State of Emergency in response to the COVID-19 pandemic pursuant to California Government Code section 8550 et seq., which remains in effect; and

WHEREAS, on March 17, 2020, Governor Newsom issued Executive Order N-29-20 that suspended the teleconferencing rules set forth in the California Open Meeting law, known as the Ralph M. Brown Act, and codified in California Government Code section 54950 et seq., provided that certain requirements were met and followed; and

WHEREAS, on June 11, 2021, Governor Newsom issued Executive Order N-08-21 which further extended the suspension of the teleconferencing rules set forth in the Brown Act and clarified that the provisions issued in N-29-20 would remain in effect through September 30, 2021; and

WHEREAS, on September 16, 2021, Governor Newsom signed Assembly Bill 361 (“AB 361”), which amended Government Code section 54953 to permit legislative bodies subject to the Brown Act to continue to meet under modified teleconferencing rules provided that they comply with specific requirements set forth in the statute; and

WHEREAS, pursuant to AB 361, a legislative body may hold an initial teleconference meeting under the modified teleconferencing rules during a proclaimed state of emergency where local officials have imposed or recommended measures to promote social distancing; and

WHEREAS, on September 30, 2021, Santa Cruz County Public Health Officer Dr. Gail Newel strongly recommended that legislative bodies in Santa Cruz County continue to engage in physical/social distancing by meeting via teleconference as allowed by AB 361 and confirmed that she will regularly review and reconsider this recommendation and notify the public when it is no longer recommended; and

WHEREAS, after its initial AB 361 teleconference meeting, a legislative body can continue to hold such teleconference meetings if a state of emergency remains active, or local officials have recommended measures to promote social distancing, if the legislative body has reconsidered the circumstances of the state of emergency and determined either that the state of emergency continues to directly impact the ability of the members to meet safely in person or that local officials continue to recommend measures to promote social distancing; and

WHEREAS, the findings set forth in the paragraph immediately above must be made within 30 days of the date the legislative body first held a teleconferenced meeting pursuant to AB 361, and every 30 days thereafter, for as long as the legislative body wishes to hold such teleconference meetings; and

WHEREAS, the Hospital has an important governmental interest in protecting the health, safety, and welfare of those who participate in meetings of the Hospital Board of Directors; and

WHEREAS, this Board finds that there is a continuing threat of COVID-19 to the community and finds that requiring all Board members to appear in-person at meetings presents greater risk to the health and safety of meeting participants stemming from reduced social distancing among people of different communities, increased exposure for those who are immunocompromised or unvaccinated, and challenges associated with fully ascertaining and ensuring compliance with vaccination, face coverings, and other safety measures at such public meetings; and

WHEREAS, this Board meets in-person in a facility where other functions take place, such that increasing the number of people present may impair the safety of participants and members of the public; and

WHEREAS, as required by AB 361, this Board has considered the circumstances of the current state of emergency and finds that the COVID-19 pandemic continues to directly impact the ability of Board members to meet safely in person and further finds that the Santa Cruz County Public Health Officer continues to recommend measures to promote social distancing; and

WHEREAS, in the interest of public health and safety, due to the emergency caused by the spread of COVID-19 the Board of Directors deems it necessary to utilize the modified teleconferencing rules set forth in AB 361.

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, for the next 30 days the Board of Directors will meet using the modified teleconference rules authorized under AB 361 and Government Code section 54953(e)(3).

Section 3. Staff is directed to return no later than thirty (30) days after the adoption of this Resolution with an item requesting the Board to reconsider the circumstances of the COVID-19 state of emergency and, if necessary, consider adoption of a subsequent Resolution to continue using the modified teleconference rules for meetings in accordance with Government Code section 54953(e)(3).

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 Hospital Corporation this _____day of _____, 2022, by the following vote:

AYES:
NOES:
ABSENT:
ABSTAIN:

_____
Chair, Board of Directors

ATTEST

_____
Clerk of the Board

APPROVED AS TO FORM:

_____
PVHCDHC Counsel

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Consent

Title: Minutes Approval: December 28, 2022 and January 15, 2023

Recommendation: Pass a Motion approving the minutes for December 28, 2022 and January 15, 2023.

Contact: Dawn Bullwinkel, Interim 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: December 28, 2022 DRAFT Minutes
B: January 15, 2023 DRAFT Minutes

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION

BOARD OF DIRECTORS

REGULAR MEETING MINUTES

December 28, 2022

1. **CALL TO ORDER-5:01 pm**
   ROLL CALL
   Present: Directors Gallagher, Pimentel, and Chair Friel and Gabriel-Cox and Nuñez arrived for Closed Session

2. **PUBLIC COMMENTS REGARDING THE CLOSED SESSION-**None

3. **CLOSED SESSION-** 5:04 p.m.
   The Board recessed to Closed Session to discuss the matters that follow:
   a) Hearings/Reports, Code 1461, 32155
      1. Report of Patient Safety and Quality Committee
      2. Report of Medical Staff Credentials Committee
      3. Report of Medical Staff Interdisciplinary Practice Committee
      4. Quality Dashboard – *staff report*

      (Executive Sponsor: Dr. Angel, COS)

OPEN SESSION CALL TO ORDER- 6:03 p.m.

4. **REPORT OUT OF CLOSED SESSION**
   Chair Friel-Board received reports

5. **CONSIDERATION OF LATE ADDITIONS TO THE AGENDA-**None

6. **PUBLIC COMMENT-**None

7. **COMMENTS FROM BOARD MEMBERS-**None

8. **REPORT FROM CHIEF EXECUTIVE OFFICER SALYER**
   CEO introduced Julie Peterson, new CFO for Watsonville Community Hospital. CEO Steven Salyer gave an operational update of hospital activities.

   June Ponce, Director of Marketing, Growth & Outreach, gave a report on activities and events for Hospital staff.

   CFO Peterson provided financial report and presented Income Statement for September – November 2022.

9. **CONSENT AGENDA**

Action: Consent Agenda

a) Board questions to staff
b) Public Comment-None
c) **MOTION:** Director Pimentel made a motion to approve the Consent Agenda, seconded by Director Gabriel-Cox, and carried by the following vote:
d) **Action by Board/Roll Call Vote**
Yes: Gabriel-Cox, Gallagher, Nuñez, Pimentel, Friel

A. RESOLUTION NO. 17-2022
Resolution Making Findings and Ordering the Use of Teleconference Meetings of the Board of Directors Due to Covid-19, Pursuant to the Requirements of Assembly Bill 361: And Direct Staff to Return Within 30 Days with a New Resolution Addressing the Need to Continue Holding Teleconference Meetings Consistent with the Requirements of Assembly Bill 361

B. Approving Minutes of November 30, 2022

C. Resolution Approving Restated & Amended 401(a) Plan to Include Pharmacists and Nursing Supervisors in the Employer Contribution

D. Approving Of Quality Dashboard – December 2022

E. Approving Policies – Policy Summary, December 2022

10. REGULAR AGENDA

A. Consideration Of Approval of Report on Behalf of Medical Committees on the Following Reports
Motion approving MEC Report, Credentials Report of December 2022 & Interdisciplinary Practice Credentials Report of December 2022

MOTION: Director Nuñez made a motion to approve the Interdisciplinary Practice Credentials Report and Credentials Report of December 2022. The motion was seconded by Director Gabriel-Cox and carried by the following vote:

Yes: Gabriel-Cox, Gallagher, Nuñez, Pimentel, Friel

B. CONSIDERATION OF APPROVAL OF 2023 BUDGET
Report by Julie Peterson, CFO Motion to approve 2023 Budget

MOTION: Director Nuñez made a motion to approve the Interdisciplinary Practice Credentials Report and Credentials Report of December 2022. The motion was seconded by Director Gabriel-Cox and carried by the following vote:

Yes: Gabriel-Cox, Gallagher, Nuñez, Pimentel, Friel

11. ADJOURNMENT

The meeting was adjourned at 6:46 p.m.

Approved: _____

John Friel, Chair

Attest: _____

Dawn Bullwinkel, Interim Clerk of the Board

PAJARO VALLEY HEALTH CARE DISTRICT HOSPITAL CORPORATION
REGULAR MEETING MINUTES

January 25, 2023

1. **Call To Order** at 5:10 pm.
   Roll Call: Present-Directors Gabriel-Cox, Gallegher, Nunez, Pimentel, Chair Friel

2. **Public Comments Regarding the Closed Session Items**: No Closed Session public comment.

3. **Closed Session**-The Board recessed to Closed Session at 6:13 pm to discuss the following matters:
   a) Hearings/Reports, Code 1461, 32155
      1. Report of Medical Executive Committee
      2. Report of Medical Staff Credentials Committee
      3. Report of Medical Staff Interdisciplinary Practice Committee
      4. Quality Dashboard – *staff report*

      (Executive Sponsor: Dr. Angel, COS)

   b) Public Employee Evaluation (Government Code Section 54957(b)(1))
      Title: CEO Metrics Assessment Update

4. **Reconvened From Closed Session** at 6:08 pm.
   Roll Call: Present- Directors Gabriel-Cox, Gallegher, Nunez, Pimentel, Chair Friel

5. **Report Out of Closed Session**: None

6. **Modifications to the Agenda**: Reordered Agenda Items at request of CEO.

7. **Public Comments on Matters Not on the Agenda**: None

8. **Comments From Board Directors**: None

9. **Report From Chief Executive Officer Salyer:** CEO Steven Salyer provided oral report on operational hospital activity.

10. **Report From Chief Financial Officer Peterson:** CFO Julie Peterson provided Financial Performance December 2022 report**.**

11. **Informational Items**

    A) Presentation By Strategic Planning Partner – The Chartis Group

12. Consent Agenda

Consent items include routine business that does not call for discussion. One roll call vote is taken for all items.

Action: Moved/Seconded: Nunez/Pimentel
Yes: Directors Gabriel-Cox, Gallegher, Nunez, Pimentel, Chair Friel

A. Resolution 001-2023 passed making findings and ordering the use of teleconference meetings of the Board of Directors due to Covid-19, Pursuant to the requirements of Assembly Bill 361; and direct staff to return withing 30 days with a new Resolution addressing the need to continue holding teleconference meetings consistent with the requirements of Assembly Bill 361.

B. Continued the approval of Minutes for December 28, 2022.

C. Motion No. 001-2023 passed approving the Quality Dashboard.

D. Motion No. 002-2023 passed approving the Agenda Format.

E. Motion No. 003-2023 passed approving the Policies/Policy Summary except for the Medical Staff Peer Review policy which is continued to a later date.

13. Regular Agenda

A. Election of Officers

1) **Motion No. 004-004 passed** selecting Director Friel as Chair.
   Action: Moved/Seconded: Pimentel/Nunez
   Yes: Friel, Gabriel-Cox, Nunez, Gallagher, Pimentel
2) **Motion No. 005-2023 passed** selecting Director Cox as Vice-Chair.
   Action: Moved/Seconded: Pimentel/Nunez
   Yes: Friel, Gabriel-Cox, Nunez, Gallagher, Pimentel
3) **Motion No. 006-2023 passed** selecting Director Nunez as Secretary.
   Action: Moved/Seconded: Pimentel/Gallagher
   Yes: Friel, Gabriel-Cox, Nunez, Gallagher, Pimentel
4) **Motion 007-2023 passed** selecting Director Pimentel as Treasurer.
   Action: Moved/Seconded: Nunez/Friel
   Yes: Friel, Gabriel-Cox, Nunez, Gallagher, Pimentel

B. Medical Committee Report on Credentials and IDP: January 2023

Action: Moved/Seconded: Gabriel-Cox /Nunez
Yes: Directors Gabriel-Cox, Gallegher, Nunez, Pimentel, Chair Friel

Motion No. 008-2023 passed approving MEC Report, Credentials Report of January 2023 & Interdisciplinary Practice Credentials Report of January 2023.

C. Contract Agreement: Group Purchasing Organization, Vizient Inc.
Action: Moved/Seconded: Nunez/ Gabriel-Cox
Yes: Directors Gabriel-Cox, Gallegher, Nunez, Pimentel, Chair Friel

Motion No. 009-2023 passed approving the execution of the Agreement with Vizient, Inc.

D. Amended and Restated Bylaws of the Hospital Corporation
Action: Moved/Seconded: Pimentel/ Gabriel-Cox
Yes: Directors Gabriel-Cox, Gallagher, Pimentel
No: Director Nunez, Chair Friel

Motion No. 010-2023 passed approving the Amended and Restated Bylaws of the Pajaro Valley Health Care District Hospital Corporation.

E. Engagement Agreement: Chartis Group – Strategic Planning

Action: Moved/Seconded: Pimentel/ Gabriel-Cox
Yes: Directors Gabriel-Cox, Pimentel, Chair Friel,
No: Gallagher, Nunez

Motion No. 011-2023 passed a) approving the proposed engagement agreement with the Chartis Group for strategic planning; and b) directing the CEO to negotiate all possible cost savings with the vendor and request the Hospital Foundation to add Strategic Planning contract funding to their initiatives.

14. Adjourned at 8:46 pm.

Approved: _____

John Friel, Chair

Attest: _____

Dawn Bullwinkel, Interim Clerk of the Board

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Consent

Title: Policy/Summaries February 2023

Recommendation: Pass a **Motion** approving the Policies and Summary Report of February 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 are provided for your approval.

Financial Impact: None.

Attachment A:
Reports

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: Feburary 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)				
Well- Newborn Feeding	NUR2860	Revised again on 11/04/22 per the Baby Friendly Reviewer guidance/request: All maternity staff and maternity care providers will be oriented to the policy upon arrival to the unit, during their initial unit orientation. Staff and providers will read and sign off on the policy.	Approved on 05/31/2022 and Exp. 05/31/2025 Revised again on 11/04/22 per the Baby Friendly Reviewer guidance/request:	Author: Nur. Perinatal Director 11/04/2022 CNO: 01/2023 PEDS: 01/26/2023 MEC: BOT:
Aquamephyton (Vitamin K), Administration of	NUR0399	To match AAP guidelines for vitamin K administration. The major change is administration within 6hrs versus our current policy of 2hrs.	Last Approved and Exp. 09/03/2021 Revised 11/2022 to match AAP guidelines for vitamin K administration.	Author: Nur. Perinatal Director 11/04/2022 CNO: 01/2023 PEDS: 01/26/2023 MEC: BOT:
Facilities				
Toxic External Atmosphere Policy	PO3004	Uploaded New Template, minor updates, code lake referenced if no longer applicable replace with appropriate code	Regulary scheduled review	Author: Facility Director 12/30/2022 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Surface Water Emergency Response Plan Policy	PO3007	Uploaded New Template, minor updates	Regulary scheduled review	Author: Facility Director 01/04/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: Feburary 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
Department Safety Practices Policy	PO4000	Uploaded New Template, minor updates	Regulary scheduled review	Author: Facility Director 01/06/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Infection Control policy	PO4001	Uploaded New Template, minor updates	Regulary scheduled review	Author: Facility Director 01/06/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Isolation Room Precautions Policy	PO4002	Uploaded New Template, minor changes	Regulary scheduled review	Author: Facility Director 01/10/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Decontamination of Equipment Policy	PO4003	Uploaded New Template, minor changes	Regulary scheduled review	Author: Facility Director 01/10/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: Feburary 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
Confined Space	PO4004	New Template, minor changes	Regulary scheduled review	Author: Facility Director 01/11/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Mold Prevention, Response and Mitigation Policy	PO4005	Uploaded New Template, minor changes	Regulary scheduled review	Author: Facility Director 01/17/2023 01/17/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Performance Improvement Program Policy	PO4006	UploadedNew Template, minor update	Regulary scheduled review	Author: Facility Director 01/23/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
General Safety Policy	PO4007	Uploaded New Template, minor update	Regulary scheduled review	Author: Facility Director 01/17/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:

WATSONVILLE COMMUNITY HOSPITAL

Watsonville Community Hospital

POLICY APPROVAL SUMMARY REPORT

Committee: BOT

Reporting Period: Feburary 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
Arc Flash Prevention Policy	PO4008	New Template, minor update	Regulary scheduled review	Author: Facility Director 01/23/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Lockout Tag-out Policy	PO4009	Uploaded New Template, minor update	Regulary scheduled review	Author: Facility Director 01/23/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Orientation of New Employees Policy	PO5000	Uploaded New Template, minor update	Regulary scheduled review	Author: Facility Director 01/23/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
In-Service Eduacation Policy	PO5001	Uploaded New Template, minor update	Regulary scheduled review	Author: Facility Director 01/23/2023 01/24/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:

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Policy Title	**Policy Number**	**Summary of Changes**	**Rationale for Change**	**Approvals & Dates**
Continuing Education	PO5002	Uploaded New Template, minor update	Regulary scheduled review	Author: Facility Director 01/25/2023 01/25/2023 VP/Sr.Leader/CEO: 02/08/2023 MEC: N/A BOT:
Medical Staff (MS)				
Medical Staff Office Policy Regarding Peer Review, Ongoing Profession Practice Evaluation (OPPE) & (FPPE)	MS2842	Updated	Redundant; process covered in Medical Staff Bylaws, Article 6 Corrective Action and Article 12 Confidentiality, Immunity and Releases. Covered in Policy MS1798 Medical Staff Credentials & Quality Review Files.	Author: Medical Staff Director 01/2023 MEC: 01/17/2023 BOT:
Laboratory (LAB)				
Release of Specimens to Law Enforcement Agencies	LAB1838	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/18/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: N/A BOT
Packing and Shipping Infectious Substances	LAB0001	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/18/2022 VP/Sr. Leader/CEO: 02/15/2023 MEC: N/A BOT

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Biological Safety Cabinet	MIC131007	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/18/2022 VP/Sr. Leader/CEO: 02/18/2023 MEC: N/A BOT
ABORh Retype	BB131.001	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 10/26/2022 COO/VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT:
Rh Immune Globulin Prophylaxis	BB2452	No changes.	Regulary scheduled review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Pending Worklog Wyndgate	BB2738	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 10/26/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Entering Results: Crossmatch Results	BB2742	Uploaded New Template. No changes	Regulary Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Transfusion Reaction: Recording Information	BB2745	Uploaded New Template. No Changes	Regulary Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Pathologist Review	BB2755	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT
Identification and Banding of Transfusion Recipients	BB2763	Uploaded New Template. No changes	Regulary Scheduled Review	Author: Laboratory Director:10/17/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Fetal Bleed Screening Test by Rosette Method	BB2800	Uploaded New Template. No changes	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Blood Bank Refrigerator Alarms and Maintenance	BB2818	Uploaded New Template. No changes	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 10/26/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Frozen Plasma Transfusion	BB2819	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 11/14/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Gel Panel AB Identification	BB2829	No changes.	Regulary Scheduled Review	Author: Laboratory Director:10/19/2022 Lab Med. Director: 11/14/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
Creatinine Clearance	CHEM2390	No changes.	Regulary Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT
Glucose Tolerance Test	CHEM2391	No changes.	Regulary 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
Procalcitonin (PCT)	CHEM2392	No changes.	Regulary Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT
Chemistry Instrument Correlation	CHEM2393	No changes.	Regulary Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 COO/CNO: VP/Sr. Leader/CEO: MEC: BOT

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Policy Title	Policy Number	Summary of Changes	Rationale for Change	Approvals & Dates
D-10 HEMOGLOBIN A1c BY BIORAD	CHEM2589	No changes.	Regulary Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO: VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT
StatSpin Express 4 Horizontal Centrifuge	CHEM2821	No changes.	Regulary Scheduled Review	Author: Laboratory Director:12/15/2022 Lab Med. Director: 12/15/2022 CNO:VP/Sr. Leader/CEO: 02/15/2023 MEC: BOT

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Well-Newborn Feeding	Policy #	NUR2860
Responsible	Women's ~~Services, IICN~~Services, IICN	~~Effective~~~~Revised/ Reviewed~~	12/2013~~4/28/22~~
		Revised/Reviewed	11/04/22

I. PURPOSE

To promote breastfeeding as the norm at Watsonville Community Hospital (WCH), in accordance with overwhelming scientific evidence that breast milk is the optimal food for infants, and that breastfeeding has health benefits for the mother, as well as benefits for the family, the society and the environment. Also, to provide breastfeeding management guidelines in accordance with the Ten Steps to Successful Breastfeeding as required by Baby-Friendly USA and as documented in the joint statement by UNICEF (United Nations Children's Fund) and the WHO (World Health Organization).

II. SCOPE

Inpatient and Outpatient Women and Children services.

III. POLICY

Step 1. Have a written breastfeeding policy that is routinely communicated to all health care staff.

a. The WCH Breastfeeding Taskforce along with the Management Team (Nursing Directors of inpatient and outpatient women and children services) will be responsible for the development, updating, evaluation and revision of the breastfeeding policy.
b. The Management Team will oversee and be responsible for assuring the implementation of the breastfeeding policy and that professional staff training needs are identified.
c. The breastfeeding policy will be reviewed and updated at least every three years if not more frequently utilizing evidence-based guidance.
d. The breastfeeding policy will be communicated to all new pertinent employees during their orientation or within six months of hire. All maternity staff and maternity care providers will be oriented to the policy upon arrival to the unit, during their initial unit orientation. Staff and providers will read and sign off on the policy.
e. The WCH Quality Improvement Team will monitor the effectiveness of the breastfeeding policy and all other related infant feeding policies and is incorporated as part of the inpatient and outpatient quality improvement process.
f. WCH will maintain a Breastfeeding Task Force. This is an interdisciplinary team comprised of, but not limited to, hospital administrators, medical staff, nursing staff, lactation staff, and dietary staff. The Breastfeeding Task Force will identify the barriers to breastfeeding that exist in the Hospital community. This team will meet quarterly to discuss breastfeeding policies and issues.
g. All staff of the hospital that potentially interacts with childbearing women and infants and/or children will have access to a copy of the breastfeeding policy.

h. Changes to the policy will be reviewed with all staff of the hospital that potentially interacts with childbearing women and infants and/or children at the staff meeting prior to the implementation of the new procedures.
i. WCH upholds the WHO International Code of Marketing of Breast Milk Substitutes by offering education and materials that promote human milk rather than other infant food or drinks and by refusing to accept or distribute free or subsidized supplies or breast milk substitutes, nipples or other feeding devices.
j. The Ten Steps and facility philosophy regarding purchase and promotion of formulas, nipples and pacifiers will be prominently displayed in all areas that serve mothers and infants and/or children.

Step 2. Train all health care staffs in skills necessary to implement this policy.

a. The Baby Friendly Task for along with the Management Team is responsible for assessing competency-based training needs related to breastfeeding.
b. They will plan, implement, evaluate and annually update this competency-based training in breastfeeding and parent teaching for formula preparation and feeding for all staff caring for mothers, infants and/or young children.
c. Training programs will vary in length and substance depending upon the level of competency required by the health care team member's function, responsibility and previously acquired training, and will include documentation that essential skills have been mastered.
d. All nursing staff in contact with mothers and infants will be required to participate in standardized breastfeeding education.
    i. Nursing staff will receive a total of 20 hours of training consisting of the 15 sessions required by Baby-Friendly USA, as defined in Guidelines and Evaluation Criteria Appendix A, plus 5-hours of supervised clinical training/Experience. Supervision will be the responsibility of designated lactation educators/nurse educators.
    ii. Ongoing education will be provided annually with demonstrated competency.
    iii. Documentation of lactation education will be maintained in employee files. Such documentation shall consist of topic, date of training, date of competency verified. Sign in sheets and certificates of attendance will be maintained on file.
e. Physicians should have a minimum of 3 hours of breastfeeding management education pertinent to their role.
f. The management team will determine the amount and content of training required by staff in other units and roles based on their exposure to mothers and babies.
g. All new employees who will have contact with mothers and infants will be required to receive appropriate lactation training as a part of their orientation. Within 6 months of their arrival, all health care professionals who will be working with mothers and infants will receive the requisite amount of training in breastfeeding management.
h. Documented lactation education and training prior to employment will be evaluated and accepted if it adheres to the requirements set forth by Baby-Friendly USA.
i. Lactation management will be included as part of the maternity staff competency evaluations for the nursing staff and performance evaluation.
j. The facility does not receive free gifts, non-scientific literature, materials, equipment, money, or support for breastfeeding education or events from manufacturers of breast milk substitutes, bottles, nipples, and pacifiers.

Step 3. Inform all pregnant women about the benefits and management of breastfeeding.

a. Lactation staff members from this facility attend the Santa Cruz County Breastfeeding Coalition meetings. Part of the responsibility of staff members who attend these meetings is to develop a relationship with local individuals and organizations that offer prenatal and postpartum breastfeeding support and to coordinate breastfeeding messages with these individuals. It is also the responsibility of the staff to discover prenatal and postpartum breastfeeding needs in the community and to encourage the development of services to meet these needs. After each meeting, staff members in attendance at the meeting will report highlights of the meeting at the facility's maternity staff meeting.
b. Triage - At prenatal service contacts conducted at this facility, pregnant women will receive patient education material which describes the benefits of breastfeeding and the practices implemented in this facility to support optimal breastfeeding outcomes. The lactation staff member will be responsible for reviewing and identifying patient education material. Staff nurses will be responsible for distributing the patient education material to pregnant women upon discharge, addressing breastfeeding concerns or questions, and documenting in the medical record.
c. Hospital Tours - At all prenatal tours conducted at this facility, pregnant women and their families will receive patient education material which describes the benefits of breastfeeding and the practices implemented in this facility to support optimal breastfeeding outcomes. The lactation staff member will be responsible for reviewing and identifying patient education material. It is expected that the staff nurse/health educator conducting the tour will discuss this information.
d. Childbirth Education- WCH perinatal education team offers free monthly prenatal breastfeeding education classes to all pregnant or recently delivered parents. The childbirth education conducted at this facility will utilize curriculum which includes the key teaching points listed in the Baby-Friendly Guidelines and Criteria for Evaluation. The lactation staff member and/or Perinatal Director will be responsible for reviewing and identifying this curriculum.
e. Minimum content for patient education must include the importance of breastfeeding, the importance of exclusive breastfeeding for 6 months and basic breastfeeding management. The time available for education at these contacts will determine the amount of education that may be conducted.
f. Topics to be addressed in classes and patient educational materials may include but are not limited to:
    - The benefits of breastfeeding for both the baby and mother
    - The recommendation of exclusive breastfeeding for the first 6 months, as well as the continuation of breastfeeding after introduction of appropriate complimentary foods and throughout the first year of life
    - Labor management techniques to allow for non-pharmacological pain relief
    - Basic breastfeeding management, including proper positioning and latching techniques, and recognition of feeding cues
    - Early initiation of breastfeeding
    - Early skin-to-skin contact
    - How to assure adequacy of milk supply, production and release
    - Hand expression of breast milk and use of pump if indicated
    - Feeding on demand; infant -led feeding
    - Frequent feeding to assure optimal milk production

- How to assess if infant is adequately nourished
- Typical infant feeding behaviors
- The couplet care unit and the importance of rooming-in on a 24-hour basis
- Psychosocial factors and socio-cultural barriers or constraints influencing the decision to breastfeed
- Dietary concerns
- Indications for supplementing breast milk
- Reasons for contacting the healthcare professional
- Individualized education when indicated on documented contraindications to breastfeeding and other medical conditions

g. The facility offers no group sessions on the use of formula or infant feeding bottles. In addition, none of the educational materials women receive at prenatal contacts (e.g., triage visits, hospital tours, childbirth education) will contain product names, images, or logos of infant formula, foods, bottles, feeding devices and other related items.

h. Employees of manufacturers or distributors of breast milk substitutes, bottles, nipples, and pacifiers will have no direct communication with pregnant women and mothers.

i. Upon admission to this facility, the admission nurse will document the mother's feeding choice for her infant.
   i. If the mother states her intention is to breastfeed her infant, the mother's history will be assessed to discover any possible contraindications for breastfeeding. If it is discovered that there is a contraindication, the mother will be counseled appropriately and supported by the nursing staff. The medical contraindication will be documented in the mother's chart.
   ii. If the mother states her intention is to formula feed her infant, the nurse will counsel the mother to ensure that she has been informed of the benefits of breastfeeding and the risk of formula feeding. The nurse will also give the mother the opportunity to ask questions regarding any concerns she may have regarding breastfeeding. If after counseling, the mother's intention is to formula feed, this choice will be supported and the education administered will be charted.
   iii. All mothers will be given the mother and baby patient education material.

Step 4 - Help mothers initiate breastfeeding within an hour of birth.

a. Definition of skin-to-skin at WCH - Skin-to-skin care is practiced by placing all infants, regardless of the feeding decision, naked prone on the mother's bare chest and/or abdomen immediately following birth. The mother will have on no clothing between herself and the infant and there will be no towel, blanket, faja or belly band between the mother and the infant to disrupt the contact of skin-to-skin care. The infant should be able to access the mother's breasts with no interference from any bras, gowns, etc. A warm blanket will be laid over the infant and mother once the infant is in place skin-to-skin. Infant and mother will be dried and remain together in this position with warm blankets covering them with infant face and shoulder visible for monitoring.

b. Vaginal Birth - Mothers who have healthy vaginal deliveries must be given their infants to hold skin-to-skin immediately, unless there is a medically justifiable reason for delay. ~~All infants, regardless of feeding decision, will be dried and immediately placed skin-to-skin, if infant and mother are stable, with no interruption~~

~~of skin-to-skin contact until the first breastfeeding occurs~~Initial skin-to-skin contact should continue uninterrupted until the completion of the first breastfeeding. ~~.~~After the first breastfeeding, skin-to-skin contact will continue as long as mother desires and is feasible for the infant. In the case ~~case where the mother chooses to~~of formula feeding infants, ~~formula feed, the~~ initial ~~period of~~ skin-to-skin contact should continue uninterrupted for ~~will last~~ at least one hour. After the initial period of skin-to-skin contact, all mothers will be encouraged to continue this type of care for their infants as much as possible during the hospital stay and taught how to recognize when their infants are ready for breastfeeding/feeding, offering help as needed.

c. Cesarean birth - Mothers who have healthy cesarean deliveries must be given their infants to hold skin-to-skin when the mother is responsive and alert, unless there is a medically justifiable reason for delay~~All infants, regardless of feeding decision, will be dried and immediately placed skin-to-skin in the operating room, if infant and mother are both responsive, alert, and medically stable~~. ~~-~~Initial skin-to-skin contact should continue uninterrupted until the completion of the first breastfeeding. In the case of formula feeding infants, initial skin-to-skin contact should continue uninterrupted for at least one hour. The infant will be naked, across mother's chest, with the face visible for monitoring. Infant may be transported skin-to-skin with caregiver to recovery room.~~ As soon as the mother and infant are in the recovery room, skin-to-skin contact will resume with no interruption until the first breastfeeding occurs~~. After the first breastfeeding, skin-to-skin contact will continue as long as mother desires and is feasible for the infant~~. In the case where the mother chooses to formula feed, the initial period of skin to skin will last at least one hour.~~ After the initial period of skin-to-skin contact, all mothers will be encouraged to continue this type of care for their infant as much as possible during the hospital stay and taught how to recognize when their infant is ready for breastfeeding/feeding, offering help as needed.

d. If mother is incapacitated, another adult such as the baby's father or designated significant other may hold the baby skin-to-skin.

e. The nursing staff present immediately after delivery has the responsibility to create the optimal environment for transition of the infant and initiation of the first breastfeeding. This encompasses placing the infant skin-to-skin with the mother immediately after birth, assisting the mother to recognize infant signs of feeding readiness and allowing the infant to self-attach to the breast.

f. Skin-to-skin initiation at birth will be documented in the baby's EMR including the time skin-to-skin begins and ends and any reason for delay of immediate skin-to-skin.

g. During the initial period of skin-to-skin contact, routine newborn procedures will be postponed until the first ~~breast~~feeding has been completed. Routine assessment procedures will be performed while the infant is skin-to-skin with mother.

h. Prophylactic ~~antibiotics~~ medications should be delayed until after the first feeding and the first hour of skin-to-skin contact.~~for the first hour after birth to allow uninterrupted mother-infant contact, bonding and breastfeeding.~~ Vitamin K and Hepatitis B vaccine may be administered while infant remains skin-to-skin.

i. Procedures requiring separation of mother and baby i.e., bathing should be delayed until after the initial skin-to-skin contact, and should be conducted at the mother's bedside whenever possible.

j. If mother and infant are separated for medical reasons, skin-to-skin contact will be initiated as soon as the mother and infant are reunited, and medical condition allows.

k. Mothers will be encouraged to hold their ~~babies~~ infants' skin-to-skin without interruption and continue until the completion of the first feeding, and as much as possible during the hospital stay unless medically and/or psychosocially contraindicated.

l. Mothers of infants who are being cared for in the ~~nursery or IICN~~Intermediate Intensive Care Nursery will be instructed and encouraged to practice skin-to-skin care as soon as the infant is considered ready for such contact. Skin-to-skin care will be documented in the baby's EMR including the time skin-to-skin begins and ends

Step 5 - Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.

a. Breastfeeding education will occur in Labor and Delivery and continue throughout the hospital stay. Discharge education booklet will be given and instructions will be reviewed prior to discharge. Topics of education include but are not limited to:
   - Techniques for proper positioning, latching and detaching
   - Milk supply within the first 2 days – production and release
   - Supply and demand principle of milk production
   - Infant feeding, frequency and readiness cues
   - Nutritive sucking and swallowing
   - How to assess if infant is adequately nourished and when to seek help from a qualified health care provider
   - Manual expression of breast milk
   - Importance of exclusive breastfeeding for the first 6 months
   - Sustaining milk supply if not exclusively breastfeeding

b. A lactation risk assessment will be completed for all couplets. The RN will review and discuss the history of maternal anatomical/physiological occurrences that may interfere with breastfeeding including but not limited to: lack of noticeable breast enlargement during puberty or pregnancy, flat or inverted nipples, breast surgery, diabetes, hypothyroidism, PCOS, glandular insufficiency, and/or infertility.

~~b.~~c. The primary nurse will provide initial lactation education.

~~c.~~d. Breastfeeding assessment/evaluation will be performed by the primary nurse after the initial lactation education is provided, within 3 hours of delivery and then a minimum of at least once every shift thereafter, including assessment for adequate milk transfer (e.g., listening to swallows, normal urine/stool output, etc.) and documented using the LATCH tool and I&O.

~~d.~~e. Mothers will be encouraged to feed according to baby's cues approximately 8-12 times in 24 hours. No staff member will place any limitations on how often or how long mothers should breastfeed. When satisfied, the newborn will fall asleep or unlatch.

~~e.~~f. WCH will maintain lactation educators who will be available to advise mothers during their hospital stay as well as in preparation for hospital discharge.

~~f.~~g. High risk and special needs mothers and infants and mothers who have breastfeeding problems and/or must be separated from their infant will be taught how frequently to express her milk as well as proper storage and handling procedures.

(Refer to separate Policy #NUR1318 Breast-milk Collection and Storage.) Referral for lactation consultation and/or pediatric consultation will be at the discretion of the primary nurse.

i. Milk expression will be started within 6 hours of birth
ii. Mothers will be encouraged to express their milk a minimum of every two to three hours or at least 8 or more times every 24 hour.
iii. Expressed milk will be given to the infant as soon as the infant is medically ready
iv. Mother's expressed milk will be used before any supplementation with formulas

h. Routine use of nipple creams, ointments, or other topical preparation will be avoided. Mothers with sore nipples will be observed for latch-on techniques and will be instructed to apply expressed colostrum or breast milk to the areola/nipple after each feeding.

i. Formula Preparation:

i. Mothers who have made the informed decision to formula feed and mothers who will be utilizing formula supplementation on discharge will be instructed in safe formula preparation. See NUR0465 Formula Prep and Storage & Preparing Infant Formula Flier.

g.

Step 6 - Give newborns no food or drink other than breast milk unless medically indicated.

a. Mothers will be encouraged to exclusively breastfeed their infants while in the hospital and to continue exclusive breastfeeding for six months.
b. Exclusive breast milk feeding is defined by the current Joint Commission Perinatal Care Core Measure.
c. Infant Mmedical contraindications when an infant may require formulato breastfeeding:

i. Galactosemia
ii. Maple Syrup Urine Disease

d. Maternal contraindications to breastfeeding include the following:

i. Mother is HIV+
ii. Maternal medications including, antimetabolites, cancer chemotherapy, some psychotropic medications and a small number of medications.

i.

iii. Active substance abuse:

- Galactosemia
- Maple Syrup Urine Disease
- HIV+
- Active substance abuseIllicit street drug and alcohol use must be evaluated on a case-by-case basis.
- Maternal use of nicotine, alcohol, ecstasy, amphetamines, cocaine and related stimulants has been demonstrated to have harmful effects on breastfed infants.

- Alcohol, benzodiazepines and cannabis can cause sedation in both the mother and the infant.
- Mothers should be encouraged not to use these substances and given opportunities and support to abstain.
- Mothers who choose not to do so should seek individual advice on the risks and benefits of breastfeeding depending on their individual circumstances.

- ~~c. Certain medications~~

~~d.~~e. Medical conditions when an infant may need supplementation include but are not limited to:

i. Newborns who are at risk of hypoglycemia due to impaired metabolic adaptation or increased glucose demand when blood glucose fails to respond to optimal breastfeeding. See NUR0349: Neonatal Asymptomatic Hypoglycemia & NUR0351 Neonatal Symptomatic Hypoglycemia

ii. Significant weight loss >10% and/or the mother's breast milk production is not established

iii. Mother's informed decision to formula feed

- ~~Medical conditions determined per protocols (e.g., hypoglycemia)~~
- ~~Per MD order/determination~~
- ~~Maternal refusal to breast feed~~

f. Formula will not be placed in or around the breastfeeding infant's bassinet or in mother's room.

~~e.~~g. Formulas will not be part of the standard orders for newborn care and will only be given to infants per physician's order. Mother will be informed of the reason formula feeding is necessitated.

~~f. Formulas will not be part of the standard orders for newborn care and will only be given to infants per physician's order and with mother's knowledge of the reason why.~~

~~g.~~h. When supplementation is medically indicated, artificial nipples will be avoided and an alternate feeding method will be utilized: finger feeding, spoon, SNS and paced bottle feeding. Education regarding options, as well as appropriate use of the feeding device, will be provided to the mother by a nurse and/or a lactation educator trained in using that method to maintain mother-infant breastfeeding skills. Care should be taken not to exceed the physiologic capacity of the newborn stomach at each feeding.

i. First 24 hours of life: 2-10ml per feeding
ii. 24-48 hours of life: 5-15ml per feeding
iii. 48-72 hours of life: 15-30ml per feeding
iv. 72-96 hours of life: 30-60ml per feeding

~~h.~~i. All efforts will be made to supplement the infant with breast milk. If the maternal milk supply is inadequate, formula will be used. Mother will be informed of the medical reason formula feeding is necessitated.

~~i.~~j. If a mother requests that her baby be given formula, the heath care staff will address the mother's concerns; provide the mother with education on the risks of introducing

formula, and the possible consequences to the health of her baby and the success of breastfeeding. If the mother still requests formula, her request should be granted and her informed decision documented.

j.k. The mother who decides to feed her infant a breast milk substitute will be given written and verbal information regarding appropriate hygiene, cleaning utensils and equipment, appropriate reconstitution, accuracy of measurement of ingredients, safe handling, proper storage, and appropriate feeding methods. This education will be documented.

k.l. Reason for supplementation and education provided will be documented.

l. Formula, nipples, bottles and pacifiers will be purchased by the medical center for patient use paying fair market value.

m. Formula will be stored in a secure location within each unit that uses it, and distribution will be monitored.

Step 7 - Practice "Rooming- -In" by allowing mothers and infants to remain together 24 hours a day.

a. Watsonville Community Hospital only provides rooming-in care for mother/infant couplets. Separation only occurs for medical reasons. Watsonville Community Hospital only provides rooming-in care for mother/infant couplets. Separation only occurs for medical

a. Accommodationsreasons.

b. Accommodations for mothers and infants to remain together 24-hours a day is the standard for mother- infant care for healthy, full-term infants, regardless of infant feeding choice and assured throughout their hospital stay, unless contraindicated. Infants will remain with their mothers (room in) at least 23 of the 24 hours per day.

c. Mother/infant dyad will be protected at all times from disruption that may impact their ability to bond or interfere with breastfeeding needs. Breastfeeding takes priority over tasks when possible. Nurses will advocate for the couplet including asking visitors to wait outside the room while mother is breastfeeding or during mother/infant bonding, or periods of rest if necessary.

d. Procedures will be performed at the mother's bedside with the focus of keeping the mother and newborn together, whenever possible. Separations should be avoided and/or absences of the newborn from the mother should not exceed one hour per day.

e. d) If maternal/infant conditions preclude rooming-in, all efforts will be made to return the infant to the mother for breastfeeding. The infant will return to the newborn nurseryIntermediate Intensive Care Nursery for care and returned to the mother when her condition stabilizes.

f.a. Watsonville Community Hospital only provides rooming-in care for mother/infant couplets. Separation only occurs for medical reasons.

g. In the case where a mother might request that her infant be cared for in the well-baby nursery, the nurse caring for the mother-infant couplet is responsible for counseling the mother regarding the reason for her request informing the mother of the benefits of having the infant room in and will document this education. If after education and support the mother chooses to have the infant taken to the nursery the nurse caring for the infant will be responsible for bringing the infant to the mother whenever the infant displays feeding cues in support of exclusive breastfeeding.

f. Whenever rooming-in is interrupted, the reason for the interruption, the location of the infant during the interruption and the time the infant leaves and returns to the mother's room will be documented in the infant's medical record.

g. Whenever parents request their infant be kept apart from them, their reasons for such care will be listened to. A careful assessment will be made to explore challenges. If appropriate, solutions will be offered to safely avoid the separation. Staff will empower the mother's informed decision by supporting her and personalizing the conversation to answer any concerns regarding following evidence-based information on the importance of rooming-in. The process and education will be documented in the infant's medical record.

h. Mothers/partners/families will be instructed on safe sleep measures to include, but not limited to the following:

i. Infant sleeps on his/her back in the bassinet/crib.

ii. Place the infant in the bassinet when mother feels sleepy. No co-sleeping.

iii. No additional items in the bassinet such as blankets, bumper, pillow, toys

~~h.~~iv. Dress the infant in sleep clothing such as a wearable blanket or onesie. Do not cover with a blanket. Do not over bundle.

Step 8 - Encourage breastfeeding on demand.

a. Mothers will be encouraged to breastfeed on demand when the baby exhibits hunger cues or signals. Mothers will be educated as to these feeding readiness cues (e.g., increased alertness or activity, mouthing, or rooting) to be used as indicators of the infant's readiness for feeding.
b. Education will be provided by the nurse and includes, but is not limited to:
    - Hunger cues
    - Frequency of feeding (8-12 times in 24 hours)
    - Sleep/feeding cycle (cluster feeding)
    - Importance of physical contact when breastfeeding.
c. No staff member will place any limitations on how often or how long mothers should breastfeed. Infants can be offered both breasts at each feeding but may be interested in feeding only on one side per feeding during the early days. When satisfied, the newborn will fall asleep or unlatch.

Step 9 - No artificial nipples, infant feeding bottles, pacifiers, or other soothers will be given to breastfeeding infants.

a. The use of pacifiers or other soothers will be delayed in breastfeeding infants until breastfeeding is well established, about one month per AAP.
b. All staff that care for mothers and infants will be given education about how the use of bottles and/or pacifiers may interfere with the development of optimal breastfeeding and with babies' suckling or demonstration of hunger cues. This education will be documented.
c. When a mother requests that her breastfeeding baby be given an artificial nipple or pacifier, the nurse will:
    i. Inform her of AAP recommendation to avoid artificial nipple or pacifier for 1 month.
    ii. Teach alternative methods of pacification and encourage to breastfeed frequently in response to baby's hunger cues.

iii. Instruct her regarding the possible negative consequences artificial nipples and pacifiers may have to breastfeeding.
iv. Document this education and outcomes in the baby's chart.

d. Infants with certain medical conditions and newborns undergoing procedures may be given a pacifier for comfort or pain management. The infant will not return to the mother with the pacifier.
e. The hospital encourages "pain-free newborn care," which may include breastfeeding during heel stick procedures.
f. Exceptions to this policy may occur when a mother must feed her newborn expressed breast milk or formula and chooses to use a bottle after being educated regarding alternative feeding devices.
g. Artificial nipples, pacifiers, other soothers, bottles and breast milk substitutes will not be included in any gift packs given to pregnant patients or breastfeeding mothers. Marketing materials and coupons for these items will be excluded as well.

Step 10 - Foster the establishment of breastfeeding support groups and refer mothers to them on discharge.

a. The designated maternity staff member will explore with the mother, significant other and other family members or support persons the plans for infant feeding after discharge.
Linguistically and culturally specific discharge planning and teaching will include:
~~v.~~ i. Information on the importance of exclusive breastfeeding up to 6 months.
~~vi.~~ ii. Signs and Symptoms of breastfeeding problems, including reasons for contacting the healthcare professional.
~~vii.~~ iii. The importance of continuing breastfeeding after the introduction of solid foods.
~~viii.~~ iv. Teaching and education resources for each mother about breastfeeding.
~~ix.~~ v. WCH breastfeeding support group (Baby Talk)
~~x.~~ vi. Referrals to Kaiser, WIC or Salud Para La Gente lactation services for, breastfeeding support and follow-up.
~~xi.~~ vii. Recommend a routine follow-up visit with the infant's health care provider in 2-3 days post discharge for all infants.
~~xii.~~ viii. Additional resources may include La Leche League, breastfeeding telephone help-lines, community-based support groups, Nursing Mother's Council, Public Health Services Agency, etc.
b. Any nursing concerns related to infant's ability to latch or effectively suckle at the breast will be communicated to the infant's healthcare provider prior to discharge.
c. Discharge planning will include resource referral phone numbers.
d. Upon discharge, mothers will be instructed to contact their healthcare provider for any concerns or questions about breastfeeding. All infants of breastfeeding mothers will be instructed to contact their healthcare provider for an appointment within 48-72 hours.
e. Staff from the lactation department will be responsible for attending the Santa Cruz County Breastfeeding Coalition meetings in order to stay current with the available postpartum breastfeeding resources. They will compile a list of resources that is to be distributed to breastfeeding mothers prior to discharge. This list is to be reviewed and updated at least annually. As representatives of the hospital the lactation staff who attend the coalition meeting will be expected to participate in activities that assess community postpartum breastfeeding support needs, discover what breastfeeding

support groups are available to breastfeeding mothers and encourage the development of breastfeeding support groups and services when needs are discovered to exist. By becoming familiar with the support services available to postpartum breastfeeding mothers in the community these coalition members from the lactation staff at the hospital will serve as the resource persons for recommending appropriate breastfeeding services to mothers and care providers when specific needs arise.

IV. REFERENCES

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- https://www.aap.org/en/patient-care/breastfeeding/policies-on-breastfeeding/
- https://www.cdc.gov/breastfeeding/index.htm
- Hale, T.W., Rowe, H. E. (2017). Hale's Medications & Mothers' Milk (17th ed). New York, NY: Springer Publishing Company, LLC.
- Joan Younger Meek, Lawrence Noble, Section on Breastfeeding; Policy Statement: Breastfeeding and the Use of Human Milk. Pediatrics July 2022; 150 (1): e2022057988. 10.1542/peds.2022-057988
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- Wilson-Clay, B., Hoover, K. (2022). The Breastfeeding Atlas (7th ed.). Manchaca, TX: LactNews Press.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Aquamephyton (Vitamin K), Administration of	Policy #	NUR0399
Responsible	Director, Perinatal Services	Revised/Reviewed	11/2022

I. **PURPOSE:**
Prevent hemorrhagic disease of the newborn

II. **POLICY:**
Aquamephyton (Vitamin K) will be administered to all newborns in accordance with the American Academy of Pediatric administration guidelines.

III. **DEFINITIONS**
~~I.~~

IV. **PROCEDURE:**

A. Administration (IM):
1. Per physician's order
2. Dosing:
    1. 0.5 to 1 mg IM for infants more than 1500 gms within 6 hours after birth
    2. 0.5 mg IM for infants 1500 gms or less, within 6 hours after birth
3. Prophylactic medications should be delayed until after the first feeding and the first hour of skin-to-skin contact. Vitamin K and Hepatitis B vaccine may be administered while infant remains skin-to-skin.

B. Documentation:
1. Utilizing bar code scanning, chart date, time, site and nurse's signature on electronic MAR
2. If parents refuse vitamin K administration:
    1. Notify physician and document in nurses notes
    2. Parents to sign Refusal to Permit Administration of Vitamin K (Aquamephyton) as an Intramuscular Injection form.

~~II.~~

~~III.~~V. **REFERENCES:**

- Ivan Hand, Lawrence Noble, Steven A. Abrams; COMMITTEE ON FETUS AND NEWBORN, SECTION ON BREASTFEEDING, COMMITTEE ON NUTRITION, Vitamin K and the Newborn Infant. Pediatrics March 2022; 149 (3): e2021056036. 10.1542/peds.2021-056036, accessed online 11/09/22

- NeoFax, Vitamin K1, Watsonville Community Hospital intranet, accessed 11/09/22

~~IV.~~ STAKEHOLDERS
VI.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Toxic External Atmosphere Policy	Policy #	PO3004
Responsible	Facilities	Revised/Reviewed	12/30/2022

I. PURPOSE

To establish procedures for responding to situations where the external atmosphere has become toxic or polluted.

II. POLICY

Toxic External Atmosphere may be caused by smoke, chemical cloud, or other pollutants, including bio terroristic agents, such that the extent of contamination becomes a significant threat to life or health.

III. DEFINITIONS

IV. PROCEDURE

1. If a toxic external atmosphere exists or is suspected, notify the following departments immediately activate the emergency response plan. Refer to the bioterrorism plan if contaminant is suspected to be bio terroristic in nature.
    a. Plant Operations
    b. Administration
    c. Nursing
    d. Surgery
    e. Respiratory Therapy
2. Facilities/Plant Operations staff shall immediately minimize air infiltration into buildings by shutting down all supply air handling equipment and closing/covering all outside air dampers and intakes (see list below).

Air Handling Units

Air Intake Location	Direct Access by Public?	Areas Served	BAS Controlled

***During times of heightened security, extra surveillance should be given to areas of air intakes, particularly those accessible by the public.**

3. Through the wall fan coil units having fresh air intakes should be turned off.
4. Medical air compressors having exterior fresh air intakes may need to be turned off or cycled. Notify Respiratory Therapy accordingly.
5. Careful consideration should be given to securing hospital entrances/exits. Activate code Lake as required.
6. Contact local authorities to determine nature and extent of contaminant

~~a. <<Enter Fire Department contact info here>>~~
~~b. <<Enter local Hazmat Team contact info here>>~~
~~c. <<Enter Police/Sheriff Department info here>>~~
~~d. <<Enter Health Department info here>>~~
~~e. <<Enter other local or regional contact info here>>~~

~~f.~~a. Watsonville Fire Station #2 370 Airport Blvd. (831)768-3200
~~g.~~b. Clean Harbors (408)451-5000
~~h.~~c. Watsonville Police Department (831)768-3300
~~i.~~d. SC County Health Department (831)454-4000
~~j.~~e. SC county Sheriff (831)454-7600

7. Once conditions have cleared, return all systems to normal operations.

V. REFERENCES

The Joint Commission Hospital Accreditation Standards, EC.02.02.01.3 Bioterrorism Plan.

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Surface Water Emergency Response Plan Policy	Policy #	PO3007
Responsible	Facilities Director	Revised/Reviewed	01/03/2023

I. PURPOSE

The purpose of the Flood Plan is to define the program to respond effectively to flood events that pose an immediate danger to the health and safety of patients, staff, and visitors. The purpose is also to protect low lying areas around the hospital property. The Flood Plan works in conjunction with the Disaster Plan which consists of a number of procedures designed to respond to those situations most likely to disrupt the normal operations of the hospital. Appropriate and timely response to a flood event is designed to assure availability of resources for the continuation of patient care. The plan also addresses the medical needs of victims of a hospital or community based incident.

Hospitals should also be able to respond to Flash Floods. Flash Floods occur suddenly, usually within 6 hours of a rain event, and result from heavy localized rainfall or levee failures. Flash floods can begin before the rain stops. Water levels on small streams may rise quickly in heavy rainstorms, especially near the headwaters of river basins. Heavy rains can also cause flash flooding in areas where the floodplain has been urbanized.

II. POLICY

The Safety Officer will work closely with the local Emergency Management and local National Weather Service to monitor the threat for local flooding.

III. DEFINITIONS

Watsonville Community Hospital is located in Watsonville in Central Coastal California. The geographical surroundings present a potential threat of flooding due to heavy rain. Watsonville, CA has a slough running through the community. In periods of heavy rain, the streams and creeks flow into the slough. Watsonville Community Hospital is not currently in a flood zone based on the assessment of the Department of the Corp of Engineers.

Effective assessment and planning will reduce the impact of flood emergencies on the quality of patient care.

IV. PROCEDURE

During periods of heavy rainfall, water threatens to fill low lying areas if adequate physical protection has not been provided. Every effort should be made to locate internal building operations out of the path of potential water flow or water accumulation, this can be accomplished by grading the surrounding land away from the building entrances, installing adequate curbing to shift the flow of water, or by installing a drainage system or sump pumps capable of removing a 100 yr. rainfall event from the affected area. If a below grade area exists, where physical protection efforts are not deemed sufficient to protect against a storm water exposure, this emergency response plan should be placed in effect during times of heavy rainfall:

1. Assignments should be made for personnel to monitor the low lying area during times of heavy rainfall on all shifts. Conditions should be monitored throughout a storm event.

   1st Shift:_____

   2nd Shift:_____

   3rd Shift:_____

2. A person in charge of activating this surface water emergency response plan should be determined and authority given to move or shut down effected equipment.

   1st Shift:_____

   2nd Shift:_____

   3rd Shift:_____

3. During rainfall, all ingress/egress to the low-lying building area should remain closed and all drains should be checked to ensure that they are not clogged. The exterior area surrounding drains should be checked and cleared of potential debris which could clog drains during a rainfall event.
4. If sump pumps are present, they should be checked to ensure they are functional and have back up power available.
5. Pay close attention to areas below grade (IT, switchgear, generators, PBX, power plant)
6. Any remaining storage and mobile equipment should be removed from the area.
7. Any available onsite actions (such as using sandbags or flood gates to block entryways) should have personnel and equipment assigned and available to act quickly during an emergency.
8. Upon water breaching the building, any electrical panels or electrical equipment in the area should be de-energized.
9. Clean up and recovery duties should be clearly written to specify personnel and actions planned to restore normal operations as soon as possible following the event.
10. Have a plan using plastic sheeting and sandbags to seal doorways to prevent water entering your hospital.
11. Put sandbags by exposed openings.
12. Before the flood, move all chemicals, such as pesticides, fertilizers, herbicides, etc. and store them in waterproof containers above flood levels.
13. If the city water is contaminated, the hospital will use bottled water until water is tested and cleared.

Additional Key Points:

- During new construction, an effort should be made to locate building areas above grade to eliminate the potential exposure to storm water accumulation.

- Avoid storing high value equipment or materials in existing below grade spaces

V. REFERENCES

Human Resources Policy and Procedure Manual

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Department Safety Practices Policy	Policy #	PO4000
Responsible	Facilities	Revised/Reviewed	01/06/2023

I. PURPOSE

To identify and educate all required responsibilities for employees regarding general safety in the Plant Operations department.

II. POLICY

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Wear suitable clothing (avoid high heels or jewelry that may catch in machinery).
2. Use appropriate personal protective equipment.
3. Keep all hand tools in safe condition. Cutting tools must be kept sharp. Be sure that all tools are clean and free from damage, grease, or corrosion. Hammers, screw drivers and similar tools need safe handles. Chisels and similar tools shall be dressed smooth and shall be free from mushroomed heads.
4. Use only non-sparking tools when working around flammable or explosive vapors or gases.
5. Extension cords for power tools shall be checked carefully, before using; to be sure they are free from defects. Use ground connectors whenever possible.
6. A toolbox is the safest way to carry tools and to keep them together on the job.
7. Never use a defective or broken ladder. Report such defects so they can be corrected, or the ladders replaced.
8. All necessary safety precautions shall be taken while window cleaning. Inspect your equipment regularly and make periodic checks of window studs and frames.
9. Do not use step ladders as straight ladders. Be sure that straight ladders have "safety feet." When setting up a straight ladder, its base shall stand not more or less than 1/4 the length of ladder from the wall.
10. Never use metal ladders when working on electrical equipment, wiring or changing light bulbs.
11. Protect your feet with safety shoes. Wear safety goggles whenever there is a possibility of foreign bodies flying in your eyes, especially when grinding or chipping. Wear sound barriers when indicated.
12. Always shut off valves or switches when working on steam and hot water pipelines or electrical switches and systems, use (LOTO) lock out tag out process. Warning tags shall also be on such switches or valves so that others will not operate them.
13. Lockout/ tag out must be used when repairing any machinery.
14. Do not overload circuits under any circumstances. Never fuse too heavily. Anyone doing Electrical work shall make certain that adequate and proper guarding is provided for all machinery in maintenance shops. Never operate equipment when guards have been removed.
15. All lacquers and thinners shall be kept only in UL approved safety cans and stored in accordance with the State or Local Fire Codes.
16. Respond as promptly as possible to request of any personnel to repair unsafe conditions.
17. Regulate hot water thermostat control so temperature does not exceed 110 degree at taps.
18. Check all wheelchairs regularly from a maintenance and safety standpoint. Are they equipped with anti-tip devices?

19. Eliminate accumulations of oily rags which could produce spontaneous combustion. Where they may accumulate provide Underwriters' Laboratories approval metal safety cans.
20. A preventive maintenance chart and periodic check system will prevent many accidents.
21. Handle all tools carefully. Tools damaged from being carelessly piled into drawers or dropped on hard surfaces can cause mishaps.
22. Clean oil or grease from a tool before using it. A tool which slips out of the user's hand is likely to cause an injury.
23. Steady and secure material to be cut, sheared, chiseled, or filed to prevent the tool from slipping.
24. Except when using a spoke shave or draw knife, always cut away from the body.
25. Take extreme care in the use of torches and soldering irons to prevent explosions and burns. Always wear protective gear. The soldering iron must be placed so that the hot point cannot come in contact with flammable material or with the body.
26. Keep floors clean and free of sawdust, scraps of wood and other objects which might cause tripping or slipping.
27. Ensure that starting and stopping switches are within immediate reach of the person operating the machine.
28. Do not leave a running machine unattended.
29. Check saws frequently for defects and cracks.
30. Always use a pusher stick to feed small pieces of stock through a saw.
31. Ensure that the upper and lower driving wheels of the band saw are completely enclosed.
32. Test band saw wheels periodically for cracks and other defects.
33. Ensure that the cutting heads of the shaper are enclosed in an adjustable guard, made of sheet metal or cast iron.
34. When removing a blade from the shaper spindle, also remove all other blades in order to prevent throwing of a blade if the machine is inadvertently started.
35. Ensure that electrical equipment is effectively grounded.
36. Ensure that the power controls are identified by appropriate color coding.
37. Gasoline powered equipment shall be operated in well ventilated areas.
38. Fuel and flammable gas cylinders are stored separately from oxidizing gas cylinders.
39. Compressed gas cylinders must be chained or secured in the upright position and kept away from heat sources.
40. Understand and practice good body mechanics.
41. Keep to the right when going down corridors. Approach all corridor intersections carefully. Be sure traffic on other side is clear when opening swinging doors. Do not open doors with equipment. Use push panel or doorknob.
42. Do not leave equipment standing in traffic lanes. Return equipment to its proper location when not in use.
43. Do not obstruct fire equipment. Know location of firefighting equipment and how to use it. Know evacuation routes and what to do in case of fire.

V. REFERENCES

The Joint Commission Hospital Accreditation Standards, EC.01.01.01, EC.02.02.01
Department of Health

VI. STAKEHOLDERS

Facilities

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Infection Control Policy	Policy #	PO4001
Responsible	Facilities	Revised/Reviewed	1/6/2023

I. PURPOSE

Provide a policy to prevent and eliminate cross-contamination of infection in the Facilities/Plant Operations Department.

II. POLICY

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Basic infection control techniques are included as part of each employee's orientation to the Hospital.
2. Rodent and pest control is provided by an outside vendor in accordance with a contract made by WCH.
3. Employees with obvious infectious conditions may be sent home by the Director of Facilities/Plant Operations. Refer to the Human Resources manual for other policies regarding employee illness.
4. Appropriate cover garments (PPE) will be worn when an employee is required to work in or about contaminated waste, sewage, etc.
5. Before entering the operating suite, labor and delivery room, nursery or isolation rooms, employees will put on appropriate cover garments as instructed by nursing personnel in those areas. Tools which must be taken into these areas shall be disinfected before entering the area, as clean as practicable.
6. Each employee will be given in-service education annually on the basic techniques of infection control and such in-service education will be documented in the employee's file.

V. REFERENCES

The Joint Commission Hospital Accreditation Standards, EC.02.02.05, HR.01.02.01, HR.01.04.01

Infection Control manual
Human Resources manual
Department of Health

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Isolation Room Precautions Policy	Policy #	PO4002
Responsible	Facilities	Revised/Reviewed	1/9/2023

I. PURPOSE

To outline steps which must be taken by Facilities/Plant Operations personnel to protect themselves and/or patients confined in isolation.

II. POLICY

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Types of isolation precautions:
    a. Protective
    b. Wound and Skin
    c. Enteric
    d. Respiratory
    e. Strict
    f. Blood
    g. Secretion
2. A sign will be posted on the door of any patient confined in isolation indicating the type of isolation precautions which must be taken.
3. Isolation precautions apply to all persons entering the patient's room for whatever reason or for however long.
4. Employees must check with nursing personnel on the unit before entering the room of any patient in any type of isolation regarding the type of protective clothing (PPE), if any, which must be worn, how it is to be disposed of when leaving the room and any other precautions which must be taken.
5. Employees must avoid contact with the patient, their bedding, dirty dressings, and other waste materials.
6. Only those tools for which a need is anticipated should be taken into an isolation room and disinfected upon leaving the room.
7. Employees must wash their hands with soap and water thoroughly upon leaving any patient room.
8. Employees must be up to date on proper donning and doffing of PPE.

V. REFERENCES

Watsonville Community Hospital Infection Control Manual
The Joint Commission Hospital Accreditation Standards, EC.02.02.05, HR.01.02.01, HR.01.04.01, IC.01.05.01, IC.02.01.01
Department Of Health

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Decontamination of Equipment Policy	Policy #	PO4003
Responsible	Facilities	Revised/Reviewed	1/10/2023

I. PURPOSE

To define a policy for proper cleaning and disinfecting tools that become contaminated after use.

II. POLICY

III. DEFINITIONS

N/A

IV. PROCEDURE

1. Tools which do not come into contact with contaminated material normally do not require decontamination.
2. Plumbing snakes, wrenches, plungers, etc. used to open drains or stopped up toilets will be considered contaminated after use.
3. All tools used in a room posted with isolation precautions should be considered contaminated.
4. Wear personal protective equipment (PPE) when working on contaminated material such as, but not limited to, sewer lines, sterilizers or when working in areas labeled isolation.
5. Place contaminated tools in a plastic bag and label “contaminated” for transport to an outside cleaning area.
6. Using an approved disinfectant hose, down tools and equipment thoroughly near a sewer drain and allow them to air dry before bringing them back into the building.
7. Disinfect or dispose of contaminated clothing or gloves promptly.

V. REFERENCES

Watsonville Community Hospital Infection Control Manual
The Joint Commission Hospital Accreditation Standards, EC.02.02.05, HR.01.02.01, HR.01.04.01, IC.01.05.01, IC.02.01.01
Department Of Health

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Confined Space	Policy #	PO4004
Responsible	Facilities	Revised/Reviewed	1/10/2023

I. PURPOSE

To establish a confined space entry program at Watsonville Community Hospital to ensure safe entry and work in permit-required confined spaces. This procedure applies to all Watsonville Community Hospital facilities and external support personnel who are required to enter, attend, or conduct air sampling in any confined space at Watsonville Community Hospital

II. POLICY

III. DEFINITIONS

- ACCEPTABLE ENVIRONMENTAL CONDITIONS - Air quality that meets the following criteria:
  - Oxygen concentration between 19.5% and 23.5%.
  - Flammable gases and vapors less than 10% of their Lower Explosive Limit (LEL).
  - Toxic material concentration less than the current Threshold Limit Value.

  (TLV) established by the American Conference of Governmental Industrial Hygienists. (ACGISH) or the legally specified Permissible Exposure Limit (PEL) listing in Subpart Z, 29 CFR 1910.
- ANALYST - Individual authorized to perform confined space entry air sampling.
- ATTENDANT - Authorized individual outside the confined space who acts as an observer of the authorized entrants.
- CONFINED SPACE - (Permit-Required) - An enclosed space that is large enough and so configured that an employee can enter and perform assigned work, has limited or -restricted means for entry or exit (some examples are Boilers, Tanks, Vessels, Large Pipes, Vaults, Pits, and Diked Areas), is not designed for continuous employee occupancy and has one or more of the following characteristics:
  - Contains or has a known potential to contain a hazardous atmosphere.
  - Contains a material or has an internal configuration with the potential of engulfment of an entrant.
  - Has an internal configuration such that an entrant could be trapped or asphyxiated by inwardly converging walls or a floor which slopes downward and tapers to a smaller cross section.
  - Contains any other recognized serious safety or health hazard.
- ENTRANT - Individual authorized to enter a confined space.
- ENTRY - Means the act by which a person passes through an opening into a confined space and includes ensuing work activities in that space. The entrant is considered to have entered as soon as any part of the entrant's face breaks the plane of an opening into the space.
- EXPLOSION PROOF - Any equipment enclosed in a case capable of withstanding an explosion of a gas or vapor inside it and preventing the ignition of a gas or vapor surrounding the equipment.
- HOT WORK - Work that involves cutting torches, arc welding, brazing, soldering and grinding or work that results in the creation of open flames, molten metal or sparks.
- IMMEDIATELY DANGEROUS TO LIFE OR HEALTH (IDLH) - Any atmosphere that poses an immediate hazard to life or produces immediate irreversible debilitating effects on health.
- INERTING - Displacement of the atmosphere by a non-reactive gas (such as nitrogen) to such an extent that the resulting atmosphere is noncombustible.

- SUPERVISOR/TASK LEADER - Any individual responsible for the employees who must enter the confined space.
- LOWER EXPLOSIVE LIMIT (LEL) - The lower limit of flammability of a gas or vapor expressed in percent of the gas or vapor in air by volume.
- PURGE - Method by which gases, vapors or other airborne impurities are displaced from a confined space.
- UNACCEPTABLE ENVIRONMENTAL CONDITIONS - Any confined space atmosphere that does not meet the requirements as listed.
- GENERIC TITLE
    a. Analyst
    b. Attendant
    c. Designee
    d. Monitor/Tester
    e. Entrant
    f. Supervisor/Task Leader
    g. Service Coordinator

IV. PROCEDURE

The staff member developing a Worker Order (WO) shall use Attachment 2 to identify if the work involves a confined space, indicate this on the WO and include a Confined Space Entry Permit (Attachment 3) with the WO.

PRE-ENTRY REQUIREMENTS

Prior to entry into a confined space the Supervisor/Tash leader shall:

a. Complete section I of the permit.
b. Review the permit conditions with the Supervisor/designee and complete section II of the permit, specify the retest frequency.
c. Ensure confined space is isolated and tagged, if required.
d. Ensure that no significant pressure differential exists across the opening, no dangerous spillage occurs when the confined space is opened.
e. Ensure that emergency communication equipment or personnel are readily available for the attendant.
f. Ensure that all requirements identified in Sections I and II of the permit are implemented prior to the initial testing of the space.
g. Ensure that a confined space entry log (Attachment 4) is attached to the permit.
h. Provide the Confined Space Entry Permit to the Supervisor and inform him that a confined space requires testing for entry.

CONFINED SPACE TESTING OF ENVIRONMENTAL CONDITIONS

1. The Analyst shall verify that all signature blocks are signed in Sections I and II of the permit.
2. The Analyst shall perform air sampling of the confined space as specified in Section III of the permit in accordance with the following steps:
    a. The Analyst shall operate Air Sampling with the appropriate procedures.
    b. The Analyst shall perform Air Sampling so as to obtain a representative sample of the space. This may be accomplished by using an extension hose or probe.
    c. IF the Analyst must enter the space to complete the testing THEN the Analyst should contact the Job Supervisor for guidance on testing methods and personal protective equipment requirements.
3. The Analyst should record date, time, analyst initials, air quality sample results and instrument number, in appropriate blocks under “Initial Air Quality Sample.”
4. Based on the limits specified on the permit for “Acceptable Environmental Conditions,” the Analyst shall proceed as follows:

a. IF all the sample results are NOT within the limits specified on the permit. THEN check the "NO" box in the block under "Acceptable Environmental Conditions" AND LEAVE THE "Do Not Enter After" block blank.
b. IF all of the sample results are within the limits specified on the permit, THEN check the "Yes" box in the block under “Acceptable Environmental Conditions” AND complete the “DO NOT ENTER.”
c. IF the "No" box under the "Acceptable Environmental Conditions" is checked THEN the following shall be performed.
    i. The analyst shall notify the Supervisor of the sample results.
    ii. The Supervisor shall post the openings of the space with "Danger - Do Not Enter-Unacceptable Atmosphere" at the openings.
    iii. IF the air sample results were unacceptable due to flammability hazards, THEN the Job Supervisor/Task Leader shall also post the openings of the space with "Danger - No Open Flames, Sparks or Spark Generating Equipment within 50 feet" of Signs.
    iv. Supervisor shall contact appropriate fire protection operations.
    v. IF the space must be purged THEN the Supervisor shall ensure that the requirements of Attachment 6, Ventilation of Confined Spaces, are met.
    vi. When the source of the unacceptable environmental condition has been eliminated, the Analyst shall re-evaluate the air in the confined space.
    vii. When the confined space air sampling meets acceptable environmental conditions, the Analyst shall sign the permit AND Notify the Supervisor that the space has acceptable environmental conditions.
d. IF Section of the permit identifies the space as a "Potential Heat-Stress Environment" THEN the Supervisor shall ensure that the environment is evaluated to determine the best source to lower the heat level to an acceptable level.
e. The Analyst shall post the permit at the openings of the space or provide the permit to the Supervisor and inform the Supervisor that the space has been tested and has acceptable environmental conditions.

PERIODIC TESTING OF ENVIRONMENTAL CONDITIONS

1. The Analyst shall perform periodic air samples of the space until job completion at the retest frequency specified in Section III of the permit.
2. The Analyst shall enter the retest results under "retest air quality samples" for each permit located at the openings of the space.
3. The Analyst shall refer to the required retest frequency and update the "Do not enter after" date and time blocks.

WORK ACTIVITIES IN CONFINED SPACES

1. The Supervisor shall ensure that the permit and the Confined Space Entry Log are posted at the openings of the space for each shift prior to entry.
2. For each shift, prior to entry into the space, the entrants and attendants shall:
    a. Read all sections of the permit and ensure that the air quality has been tested within the period specified on the permit and that the "yes" box under "Acceptable Environmental Conditions" has been checked.
    b. Verify that the requirements identified in Sections I and II of the permit have been implemented.
    c. Complete the Confined Space Entry Log.
3. Requirements of the Attendant:
    a. Maintain communication with the entrant(s) through visual, verbal, signal, or other equivalent means.
    b. Remain outside the confined space unless replaced by another authorized attendant or for self-preservation.

   c. Order entrants to exit the space at the first indication of a condition that may threaten their safety. This includes, but is not limited to:
      i. Alarms
      ii. Unusual conduct of entrants
      iii. Situations occurring outside the space that could pose a hazard to the entrants
      iv. Initiate emergency procedures by calling the Emergency Rescue Team and follow the Emergency Procedures
4. Requirements of Entrants:
   a. Wear all required Personal Protective Equipment (PPE), as specified on the permit.
   b. Do not enter a confined space without an attendant present.
   c. Do not enter a confined space with a revoked permit.
   d. Do not enter a confined space identified as having unacceptable environmental conditions.
   e. Do not enter a confined space that does not have a current air quality sample.
   f. Maintain communication with the attendant.
   g. Exit the space when directed to do so.
   h. Conduct work activities safely in accordance with established guidelines, permits and procedures.
5. The Attendant shall notify the Supervisor prior to conducting welding, cutting, grinding, painting, cleaning or using any chemicals in the confined space.
6. Hot-work performed in a confined space shall be in accordance with Attachment 7, Hot-Work in Confined Spaces.
7. When natural lighting is inadequate for work in a confined space, appropriate auxiliary lighting for service in the confined space shall be used and shall meet the requirements of Attachment 8, Lighting in Confined Spaces.
8. When electric power tools or equipment are used in a confined space, the following guidelines shall be observed:
   a. Electric power tools shall not be used in potentially flammable atmospheres.
   b. Electric power tools used in wet confined spaces shall be equipped with ground fault circuit interrupter (GFI).
9. If additional ventilation equipment is required to meet the acceptable environmental conditions, the air in the confined space shall be monitored continuously by the Analyst.

EMERGENCY PROCEDURES

1. All entrants shall immediately exit the Confined space at the first indication of any hazard to their safety. These indications include, but are not limited to:
   a. Dizziness, mental confusion, nausea, or headaches
   b. Chemical Spills
   c. Fire
2. All entrants shall immediately exit the confined space if ordered to do so by the attendant.
3. If an entrant becomes incapacitated while in the confined space, the other entrants in similar danger shall exit the confined space.
4. In an emergency, the attendant shall:
   a. Report or direct another person to report the emergency using the in-house communication system or the Emergency Telephone Number
   b. Provide all information necessary for appropriate response organizations.
5. Under no circumstances shall anyone enter a confined space to rescue an unconscious person without the following:
   a. Self-contained breathing apparatus (SCBA)
   b. Safety harness and lifeline.
   c. Additional rescue personnel similarly prepared in a safe area outside the confined space.
   d. Communications established between entering rescue personnel and outside personnel.

ENTRY INTO CONFINED SPACES HAVING UNACCEPTABLE ENVIRONMENTAL CONDITIONS

1. The Supervisor shall determine respirator selection in accordance with hospital policy.
2. Where the confined space environment is Immediately Dangerous to Line and Health, the Supervisor shall be notified before and after entry and the following shall be used:
    a. SCBAs or air-line respirators with escape bottles
    b. Safety harnesses with attached lifelines or the equivalent
    c. At least one standby person in a safe area with a SCBA and safety harness and lifeline donned and ready
    d. At least one additional attendant
    e. At least three additional SCBAs
3. Where the confined space environment contains a flammable gas concentration greater than or equal to 50% LEL and ventilation does not reduce the concentration, the confined space should be inerted until the oxygen concentration falls below 15% prior to entry. This atmosphere is now Immediately Dangerous to Life and Health.
4. Where the confined space environment contains a flammable gas concentration between 10% and 50 % LEL, the following conditions shall be met:
    a. All portable electrical apparatus, except those certified as intrinsically safe or explosion-proof, shall be disabled or removed
    b. All tools and PPE shall be non-sparking
    c. No hot work shall be performed
    d. Appropriate respirators shall be worn as determined by the Supervisor
5. Where the confined space environment contains a toxic material concentration greater than the acceptable TLV or PEL, but not Immediately Dangerous to Life and Health, the following shall be used.
    a. Appropriate respirator as determined by the Supervisor

CLOSURE REQUIREMENTS

1. The Supervisor shall ensure that all debris, tools and chemicals are cleaned up and removed from the confined space
2. The Supervisor shall:
    a. Complete and sign Section IV of the permit

RECORDS

1. The following quality assurance records are completed by this procedure and should be submitted to the Service Coordinator for filing.
    a. Confined Space Entry Permit
    b. Confined Space Entry Log
    c. Confined space Entry Permit Tracking Log

ATTACHMENT 2: CONFINED SPACES AT Watsonville Community Hospital

This list contains all know Permit-Required Confined Spaces at Watsonville Community Hospital

MAIN HOSPITAL BUILDING

AUXILIARY BUILDING

PROFESSIONAL BUILDING

STORAGE FACILITY/BUILDING

PROTECTED AREA OUTER GROUNDS

OUTSIDE OF PROTECTED AREA/GROUND

PERMIT NUMBER

Space:_____ Space Location:_____

Department/Unit:_____Date:___/____/____

Originator:_____ Permit Expiration (Date/Time)

Description of Work to be Performed:

NATURE OF HAZARDS IN SPACE:
___ Oxygen deficiency/excess
___ Flammable Material
___ Corrosive Material
___ Toxic Material
___ Mechanical Hazards
___ Electrical Shock
___ Materials Harmful to the Skin
___ Engulfment
___ Heat-Stress Environment
___ Pressure System Environment
Other:

PREPARATION & ISOLATION:
___ Notify Affected Departments of Entry
___ Locked and Tagged - Electrical
___ Locked and Tagged - Mechanical
___ Cleaned, Drained Purged & Washed
___ Ventilated to Provide Fresh Air
___ Emergency Response Team Available
___ Emergency Informed of Specific Confined Space Hazards
___ Procedures Reviewed with Each Employee
___ Atmospheric Test for Compliance
___ Low-Voltage/Explosion-Proof Lighting
___ Ground Fault Circuit Interrupters
___ Non Sparking Tools
___ Other:

PERSONAL PROTECTIVE EQUIPMENT
___ Hard Hat
___ Safety Glasses
___ Goggles
___ Face Shield
___ Hearing Protection
___ Gloves
___ Respirator
___ Safety Harness/Life-Line
___ Clothing
___ Footwear
___ Other

AUTHORIZED ENTRANTS: (see roster)

AUTHORIZED ATTENDANTS:

SECTION II

Supervisor Review (Comments)

Date ___/___/___

SECTION III

	ALLOWABLE LIMITS	CHECK IF REQUIRED	INSTRUMENT ID NUMBER	INITIAL RESULTS Date: Am/pm	RESULTS-1 Date: Am/pm	RESULTS-2 Date: Am/pm
Oxygen-Min	19.5%					
Oxygen-Max	23.5%					
Flammability	<10%					
CO	<35ppm					
H2S	<10 ppm					
CL2	<0.5%					
CLO2	<0.1ppm					
SO2	<0.1ppm					
Heat						
Other						
ACCEPTABL E ENVIRONMENTAL CONDITION S?			YES NO	YES NO	YES NO	YES NO
DO NOT ENTER AFTER:			Date & Time	Date & Time	Date & Time	Date & Time

Name of employee conducting atmospheric monitoring_____.

SECTION IV -- Authorization: I certify that all required precautions have been taken and the necessary equipment has been provided for safe entry and work in this confined space. Name: (Print)_____ Signature:
Time:_____ Date:_____

ATTACHMENT 4: CONFINED SPACE ENTRY LOG

CONFINED SPACE ENTRY LOG Location_____ Permit Number_____

Signing the confined space entry log indicates that the employee has read and understands the confined space entry permit.

Name Last	First	Signature	Company	Time Reviewed	Date Reviewed

ATTACHMENT 6: VENTILATION OF CONFINED SPACES

1. It may not always be required, but it is good work practice to ventilate any confined space prior to entering and during occupancy. Radiation protection should be implemented when ventilation is required in a radiology restricted area.
2. Whenever a ventilation system is employed, the system shall be evaluated before and periodically during each work shift as deemed necessary by the Supervisor. Ventilation equipment used to prevent situations that pose immediate danger to life or health should have an audible warning device or employee assigned to continuously monitor and to signal ventilation system failure.
3. Continuous general dilution or local exhaust ventilation shall be maintained where unacceptable environmental conditions may be produced as part of a work procedure (for example, cleaning with solvents, welding, or painting), or where unacceptable environmental conditions may develop due to the nature of the confined space (for example, desorption from walls or evaporation of residual chemicals). Even though supplied-air or self-contained breathing equipment may be employed during entries, sufficient ventilation is required to dilute any combustibles to safe levels. If dilution is ineffective in reducing combustibles to safe levels, then the space shall be inerted, considered IDLH.
4. The density of the contaminant and the configuration of the confined space shall be considered in determining the ventilation technique to be employed.
5. Low-suction-pressure-type air movers shall be used to purge containers that are constructed of light gauge metal or air flow rate shall be controlled to preclude collapse of the container.
6. When flammable contaminants are to be purged, ventilation equipment designed for use in hazardous locations shall be employed and precautions taken to eliminate all sources of ignition.
7. Pure oxygen (sometime improperly called “air”) shall not be used to ventilate confined spaces.
8. The Supervisor or designee shall check on a schedule frequency to ensure that contaminated air from the confined space is exhausted to a location where it presents no hazard to employees or equipment. Any hazardous concentrations shall be diluted by the use of blowers, or exhausted as necessary, or appropriate respiratory protection equipment shall be worn as determined by the Supervisor.

ATTACHMENT 7: HOT WORK IN CONFINED SPACES

1. A Hot Work Permit shall be obtained as required.
2. If the confined space last contained a flammable gas, liquid or vapor, hot work shall not be started in or on a confined space until the space has been cleaned or inerted.
3. Combustibles and ignition sources shall be controlled.
4. When welding is suspended for more than 30 minutes, the power source to the machine shall be de-energized, all electrodes removed from holders and the holders placed so accidental contact cannot occur.
    a. All gas or oxygen cylinders and manifolds shall be located outside the confined space.
    b. When gas welding or cutting is suspended for more than 30 minutes, but less than 2 hours, the torch and hose also shall be removed from the confined space. When the work is suspended for more than 2 hours, the regulators are to be removed from the cylinders and the cylinders capped.
5. Before welding, cutting, or heating is started on a surface covered with a preservative or protective coating, the flammability and thermal decomposition products of the coating shall be considered as follows:
    a. Flammability coatings shall be stripped from the area of hot work to prevent ignition.

   b. In confined spaces, all surfaces covered with coatings that would decompose under hot work into toxic, corrosive, or irritant components shall be stripped from the area of heat application. Otherwise, employees shall wear respirators.
   c. Hardened preservative coatings and lining shall not be removed by heat unless there is sufficient local mechanical exhaust ventilation to remove fumes and smoke at the source.
   d. Flames shall not be used to remove soft and greasy coatings
6. Continuous ventilation may be required. The Supervisor should be contacted for guidance.

ATTACHMENT 8: LIGHTING IN CONFINED SPACES

When natural lighting is inadequate for work in confined spaces, appropriate auxiliary lighting for service in the confined space shall be used and meet the following requirements

1. Temporary lighting shall be equipped with guards to prevent accidental contact with the bulb; however, guards are not required when the bulb is deeply recessed within the reflector.
2. Temporary lighting shall be equipped with flexible electric cords, with connections and insulation maintained in a safe condition and equipped with ground continuity monitors.
3. The lighting shall not be suspended by the electrical cords, unless designed for suspension.
4. Cords shall be kept clear of working spaces and walkways or other locations in which they may be exposed to damage.
5. Battery or low-voltage (12v or 6v) lighting systems with ground fault circuit interrupters shall be used for work in wet confined spaces, in confined spaces partly filled with liquid and on the water side of boilers.
6. Explosion proof, low voltage (12v or 6v) lighting systems with ground fault circuit interrupters shall be used for work in confined spaces with potentially flammable atmospheres.
7. In the absence of temporary lighting, employees shall not be permitted to enter dark confined spaces without flashlights and the use of matches and open-flame lights shall be prohibited.

V. REFERENCES

OSHA 29CFR
29 CFR 1910.94, Ventilation
29 CFR 1910.134, Respiratory Protection
29 CFR 1910.146, Permit-Required - Confined Space Entry
   a. Control of Transient Combustibles
   b. Control of Ignition Sources
   c. Foreign Material Exclusion
   d. Safety Tagging
   e. Control of Work
   f. Selection and Issue of Respiratory Protection Equipment
   g. Heat Stress Management
   h. General Safety Precautions

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Biological Safety Cabinet	Policy #	MIC131007
Responsible	Laboratory Director	Revised/Reviewed	10/18/2022~~08/14/2020~~

I. PURPOSE

The biological safety cabinet (BSC) is the most important primary containment equipment in the clinical microbiology laboratory. Class II Type A laminar-flow cabinets are the most commonly used for BSL 2 and 3 practices. This facility uses a Class II Type A BSC.

II. POLICY

Air is drawn into the cabinet by negative air pressure and passes through a HEPA filter. The air flows in a vertical sheet that serves as a barrier between the outside and the inside of the cabinet. The cabinet exhaust air is also passed through HEPA filters. Aerosols are contained within the BSC, and the work area is protected from outside contamination when the cabinet is operating under the manufacturer's recommended conditions.

III. REAGENTS

N/A

IV. STORAGE

N/A

V. SPECIMEN

N/A

VI. QUALITY CONTROL

Daily

1. Disinfect all cabinet surfaces while cabinet is running
2. Check air flow and record measurement on the Microbiology Temperature Monitoring Log. Air flow range is 0.4 – 0.7 psig.

Monthly - Clean the gutter area.

Annually - Have BSC certified to meet Certification of Environmental Compliance.

VII. PROCEDURE

Start-up

1. Turn on blowers for at least 10 minutes before QC checks and specimen processing.
2. Open to operating height.
3. Turn on the lights
4. Perform daily QC.
5. Clean the cabinet working surfaces.

Operation

1. Avoid outside sources of air currents (e.g., personnel walking by, doors being opened or closed, etc.).
2. Wear long-sleeved coats or cuffed gowns and gloves during specimen processing.
3. Place all items that will be used inside the cabinet prior to starting work.
    a. Segregate clan from contaminated materials.
    b. Place a minimum number of large items inside the cabinet
        i. *Do not* block intake or rear grills.
        ii. *Do not* place sterile material or specimens near the sides, front, or back of the cabinet.
        iii. *Do not* place or tape paper notes or procedures on the window.
        iv. *Do not* use a flame in the cabinet.
        v. *Do not* operate centrifuges in the cabinet.
4. Plan work flow to minimize movements.
    a. Work at least 6 inches inside the front grill intake.
    b. Avoid rapid arm movement in and out of the cabinet while a procedure is in process.
    c. If necessary, slowly move arms in and out of the cabinet.

Shutdown

1. Allow the cabinet to continue running for 15 to 20 minutes after work is completed before removing materials.
2. Allow the cabinet to continue running for at least 3 hours after processing fungal specimens.
3. Place contaminated materials in covered containers or closed bags, or immerse them in disinfectant, before removal from the cabinet.
4. Disinfect the surfaces of any contaminated materials before removal from the cabinet.
5. Clean up spills by following the steps outlined in the Safety Basics policy.
6. Clean interior surfaces with disinfectant.
7. Turn off the blower.
8. *Do not* shut down cabinets that function 24 hours a day, unless a malfunction occurs or routine maintenance is required.

VIII. INTERPRETATION

N/A

IX. REPORTING RESULTS

N/A

X. LIMITATIONS

- BSCs should not be used as fume hoods
    - Toxic, radioactive, or flammable vapors or gases are not removed by HEPA filters.
    - Potentially hazardous amounts of volatile material may build up in class II type cabinets.
    - Exhausted vapors can be vented into the laboratory air.
- The use of gloves when performing routine manipulations should not substitute for proper hand washing practices. Wash hands with soap and water between tasks and when heavily soiled with clinical material.

XI. REFERENCES

1. Clinical Microbiology Procedures Handbook, 4th Edition (ASM Press) by Leber, Amy L.

XII. ATTACHMENTS

Microbiology Temperature Monitoring Log
G:\Micro\Checklists\Lab Tech\Microbiology Temperature Monitoring Log

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Mold Prevention, Response and Mitigation Policy	Policy #	PO4005
Responsible	Facilities	Revised/Reviewed	1/12/2023

I. PURPOSE

1.0 This program provides guidelines for the prevention and control of mold growth in Watsonville Community Hospital buildings, and corrective action protocols. The objective of the program is to develop a proactive approach to controlling mold growth such that building systems and building environments are not impacted. This program:

Provides basic information and tools to educate building managers and occupants and Provides guidance to WCH personnel responsible for maintaining building systems regarding prevention and control of mold growth, and for implementing appropriate corrective actions as warranted.

II. POLICY

OPERATIONS & MAINTENANCE MOLD CONTROL PROGRAM FOR WCH

III. DEFINITIONS

N/A

IV. PROCEDURE

2.1 Molds (also referred to generically as “microbes”) are found in all environments, indoors and outdoors, in homes, hospitals, and workplaces. Molds live in soil, on plants, and on dead and decaying organic matter. Molds spread by releasing spores, and they then usually settle onto surfaces of all types. “Mildew” is a general term for various species of mold that commonly grows on fabrics, windowsills, bathroom, tiles, etc. Another familiar type of mold is Penicillium, from which the widely used antibiotic penicillin is made.

2.1.1 Health Effects

Molds have always existed alongside humans in the environment without causing ill effect. Experts agree molds only present a potential health impact when they are present in very large concentrations, or when certain individuals, such as asthmatics, have prior sensitization to specific types of molds.

Molds
There are no regulated or generally accepted limits for concentrations of mold. Some of the more common molds found indoors and outdoors throughout the United States are Aspergillus, Penicillium, Alternaria, and Cladosporium. A few molds, under certain conditions, can cause infectious disease. Certain species of Aspergillus, for example, can cause serious disease in hospital patients who are being treated for cancer with chemotherapy. However, exposure to this common mold, even at high concentrations, is unlikely to cause infection in a healthy person.

2.1.2 General Information on Prevention and Control
Since molds generally only have the potential to cause problems when present in large numbers, the best way to prevent problems is to keep microbes from amplifying (i.e., spreading in large numbers) in the home and workplace.

Mold Control
Molds, (also called fungi), need two things to survive and grow – food and moisture. Because mold "feeds" on most organic materials, (including dirt and dust), it is virtually impossible to prevent mold amplification by eliminating its food source. Experts agree the best way to prevent mold from spreading is to correct moisture problems before they create an environment that encourages mold growth by means such as:
• Repairing plumbing leaks and leaks in the building envelope,
• Controlling condensation,
• Maintaining indoor humidity at or below 60%, and
• Drying and cleaning wet or damp areas within 48 hours of occurrence.
Specific ways to prevent and control mold growth are presented in Section 3.0.

2.1.3 General Information on Corrective Action
A visual inspection is the most important initial step in identifying a possible amplification problem. The extent of any water damage and microbial growth should be visually assessed. Building conditions supporting microbial growth must be corrected as rapidly as possible in order to prevent amplification. Repair of the defects that led to water accumulation, (or elevated humidity), should be conducted in conjunction with, or prior to, implementing the corrective actions detailed in Section 4.0. Specific methods of assessing and addressing microbial growth should be based on the extent of visible growth and underlying damage to building materials. The simplest and most expedient response that is reasonable, and properly and safely removes fungi, should be used.

Specific Watsonville Community Hospital Corrective Action Protocols are provided in Section 4.0. In general, for all response actions, the use of respiratory protection, gloves, and eye protection is recommended. Extensive growth, particularly if heating, ventilating and air conditioning (HVAC) systems should be assessed by an experienced health and safety professional and remediated by personnel with training and experience in handling materials damaged by microbial growth. Lesser areas of impact can usually be assessed and corrected by building maintenance personnel. In order to prevent growth from recurring, underlying defects causing moisture buildup and water damage must be addressed. Effective communication with building occupants is an essential component of all remedial efforts.

Bulk or surface sampling is not necessary to undertake corrective action and should not be conducted without prior approval of a Regional Engineer. Corrective actions to address visually identified microbial growth should proceed without further evaluation. Air sampling for microorganisms should not be part of a routine assessment. This is because decisions about appropriate remediation strategies usually can be made on the basis of a visual inspection. In addition, air-sampling methods for some microorganisms are prone to false negative results and, therefore, are difficult to use to definitively rule out the presence of airborne microbes.

2.2 EDUCATIONAL TOOLS

2.2.1 A Fact Sheet on Microbial Issues in the <<Hospital>> Building Environment
A fact sheet that can be disseminated to building occupants and other interested parties concerning molds is presented in Appendix A.

3.0 POLICY
The key to prevention and control of growth of molds is proper maintenance of building materials and systems. Even though federal and state regulations dealing specifically with molds do not exist at this time, the Environmental Protection Agency (EPA) has issued general guidance for how to deal with mold in schools and commercial buildings. Also, the New York City Department of Health has developed Guidelines on Assessment and Remediation of Fungi in Indoor Environments. This WCH program has been developed by incorporating information from these sources, as well as others, to provide WCH with the most appropriate recommendations for their buildings.

3.1 GUIDELINES FOR THE PREVENTION OF MICROBIAL GROWTH THROUGH THE PROPER MAINTENANCE OF BUILDING MATERIALS AND SYSTEMS
It is important to remember that mold growth occurs when moisture problems are not addressed promptly and properly. In all situations, the underlying cause of water accumulation must be rectified or microbial growth will recur. Any initial water infiltration should be stopped, and the affected areas cleaned immediately. An immediate response (within 24 to 48 hours) and thorough clean up, drying, and/or removal of water damaged materials will prevent or limit microbial growth. If the source of water is elevated humidity, relative humidity should be maintained at levels below 60% to inhibit mold growth. Emphasis should be on ensuring proper repairs of the building infrastructure, so that water damage and moisture buildup does not recur. There are many potential sources of moisture that can lead to microbial growth. Following is a list of some potential sources.

- Roof leaks
- Moisture penetration through the building envelope
- Plumbing leaks
- Uncontrolled condensation
- Improper foundation drainage
- Damp or wet locations (such as restrooms, etc.)
- Sewage leaks/spills
- HVAC condensate drip pans and drain lines
- Closed water systems
- Cooling towers

To reiterate, the key to prevention of growth of molds is proper general building maintenance. Proper maintenance will lead to fewer moisture problems, and thus, fewer microbial growth problems within a building. General building maintenance needs to include quick response to moisture problems, proper air filter changes, proper cleaning of air handling units, and proper treatment of building water systems, such as cooling towers and recirculated systems.

3.2 MICROBIAL GROWTH PREVENTION CHECKLIST AND TIPS
A checklist has been developed to assist in the identification of conditions that could lead to the growth of molds. This checklist, Mold Growth Prevention Checklist, is contained in Appendix B. In addition to the checklist, which provides a detailed list of conditions, presented below is a summary of general conditions that must be addressed to prevent mold and growth.

<u>Mold and Growth Prevention Tips</u>
- Repair plumbing immediately.
- Repair compromised seals in the building envelope as soon as possible.
- Watch for condensation and wet spots. Repair sources of moisture problems as soon as possible.
- Keep heating, ventilating and air conditioning (HVAC) drip pans clean, flowing properly,

- and unobstructed.
- Maintain low indoor humidity, below 60% relative humidity, ideally 30-50%, if possible.
- Perform regularly scheduled building/HVAC inspections and maintenance.
- Clean and dry wet or damp spots within 48 hours of occurrence.
- Don't allow foundations to stay wet. Provide drainage and slope the ground away from the foundation.

The EPA in March 2001 released a guidance document entitled Mold Remediation in Schools and Commercial Buildings. This EPA document provides recommendations for responding to water damage within 24 to 48 hours to prevent microbial growth. The following table is taken from this EPA document and is augmented with additional recommended practices from other sources. These guidelines are designed to help avoid the need for corrective action to address mold growth by taking quick action before growth starts. It is important to emphasize that the guidelines presented in the table are designed to prevent mold growth. If mold is already visible on the materials listed in the table OR the materials have been wet for longer than 48 hours, corrective action needs to be implemented in accordance with Section 4.0 protocols. Depending on the type of mold, visible mold growth will appear in different colors and textures. Commonly, mold growth appears as dark spots. In some occasions the mold growth may appear red, green or other colors. Depending on the size of the area involved and resources available, professional assistance from an experienced health and safety professional may be needed to dry an area quickly and thoroughly.

Table 1. Recommendations for responding to water damage within 24 to 48 hours to prevent microbial growth

Water damaged materials	Actions
Books & Papers	• **For non-valuable items, discard books and papers** • **Photocopy valuable/important items, discard originals** • **Freeze (in frost-free freezer) or freeze-dry**
Carpet & backing dry within 24-48 hrs.	• **Remove water with water extraction vacuum** • **Reduce ambient humidity levels with dehumidifier** • **Accelerate drying process with fans**
Ceiling Tiles	• **Discard & replace**
Cellulose insulation	• **Discard and replace**
Concrete or cinder block surfaces	• **Remove water with water extraction vacuum** • **Accelerate drying process with dehumidifiers, fans and/or heaters**
Fiberglass insulation	• **Discard and replace**
Flooring (hard surface – vinyl tile, linoleum)	• **Vacuum or damp wipe with water and mild detergent and allow to dry; scrub if necessary** • **Check to make sure under flooring is dry; dry under flooring if necessary**
Non-porous, hard surfaces (plastics, metals)	• **Vacuum or damp wipe with water and mild detergent and allow to dry; scrub if necessary** • **If possible equipment should be moved to a controlled environment, away from occupied spaces, for drying.**
Upholstered furniture	• **Remove water with water extraction vacuum** • **Accelerate drying process with dehumidifiers, fans and/or heaters** • **If possible, furniture should be moved to a controlled environment, away from occupied spaces, for drying.** • **May be difficult to completely dry within 48 hrs.**

	• **Consult a restoration/water damage professional who specializes in furniture**
Wallboard (drywall and gypsum)	• **May be dried in place if there is no obvious swelling and the seams are intact. If not, remove, discard and replace** • **Ventilate the wall cavity if possible. Ventilation should be directed to the outside via ducted fans unless it is known that no growth exists in the cavities.** • **FEMA1 recommends that flood-soaked gypsum board be removed and thrown away since floodwaters are frequently contaminated with bacteria and fungi that can cause illness. FEMA also recommends visually inspecting wet gypsum board which has been exposed to clean water for signs of damage. In the absence of damage which would make removal necessary, wet gypsum board can generally be salvaged**
Window drapes	• **Follow laundering or cleaning instructions recommended by the manufacturer**
Wood surfaces	• **•Remove moisture immediately and use dehumidifiers, gentle heat and fans for drying** • **Treated or finished wood surfaces may be cleaned with mild detergent and clean water and allowed to dry** • **Wet paneling should be pried away from wall for drying**

4.0 INVESTIGATION GUIDELINES

4.1 VISUAL INSPECTION

A visual inspection is the most important initial step in identifying a possible amplification problem. The extent of any water damage and microbial growth should be visually assessed. This assessment is important in determining remedial strategies. Heating ventilation and air conditioning (HVAC) systems should also be visually checked, particularly for damp filters, damp conditions elsewhere in the system, and overall cleanliness. Ceiling tiles, gypsum wallboard (sheetrock), cardboard, paper, and other cellulose containing materials should be given careful attention during a visual inspection. The use of equipment such as a bore scope, to view spaces in ductwork or behind walls, or a moisture meter, to detect moisture in building materials, may be helpful in identifying hidden areas of microbial growth and the extent of water damage.

In most cases corrective action can be performed using only information obtained from a visual inspection. In rare instances, however, additional information should be obtained by obtaining and analyzing bulk and/or air samples.

4.1.2 Bulk Sampling and Air Sampling

Bulk and Air Sampling should be only considered: after consultation with Regional Engineer Microscopic identification of the spores and colonies requires considerable expertise. These services are not routinely available from commercial laboratories. Documented quality control in the laboratories used for analysis of the bulk/surface, water and air samples is necessary. The American Industrial Hygiene Association (AIHA) offers accreditation to microbial laboratories (Environmental Microbiology Laboratory Accreditation Program (EMLAP)). Accredited laboratories must participate in quarterly proficiency testing (Environmental Microbiology Proficiency Analytical Testing Program (EMPAT)).

General protocols for performing bulk and air sampling are described below and are to be conducted only by a qualified consultant.

4.1.2.1 Bulk Sampling

Bulk sampling consists of sampling of building materials, surfaces, and/or water to identify specific microbial contaminants as part of a medical evaluation if occupants are experiencing symptoms which may be related to microbial exposure or to identify the presence or absence of microorganisms if a visual inspection is not conclusive.

An individual trained in appropriate sampling methodology should perform all microbial sampling. Bulk samples are usually collected from visibly moldy surfaces by scraping or cutting materials with a clean tool into a clean sample container. Surface samples are usually collected by wiping a measured area with a sterile swab or by stripping the suspect surface with clear tape. Surface sampling is less destructive than bulk sampling. Water samples are collected using a sterile sample container typically containing a preservative. Other sampling methods may also be available. A laboratory specializing in microbial sample analysis should be consulted for specific sampling and delivery instructions.

4.1.2.2 Air Sampling

To provide useful data, air sampling must be used correctly, and the data must be interpreted by a health and safety professional experienced in indoor microbial investigations.

Air sampling may be necessary if an individual(s) has been diagnosed with a disease that is, or may be, associated with a microbial exposure (e.g., pulmonary hemorrhage/hemosiderosis, and aspergillosis). Also, a significant increase in allergy symptoms by a building population, in the absence of visible microbial amplification or other explanation (e.g., the season of the year, flu epidemic, etc.), may indicate the need for air sampling.

Air sampling may also be necessary if there is evidence from a visual inspection or bulk sampling that ventilation systems contain growth or are spreading microbes from other sources of mold growth. The purpose of such air monitoring is to assess the presence and concentrations of airborne microbes in a building, or part of a building. It is preferable to conduct sampling while ventilation systems are operating.

If air sampling is performed, for comparative purposes, outdoor air samples should be collected concurrently at an air intake, if possible, and at a location representative of outdoor air. For additional information on air sampling, refer to the American Conference of Governmental Industrial Hygienists' document, "Bio-aerosols: Assessment and Control."

4.1.2.3 Interpretation of Data

Evaluation of bulk, surface, water, and air sampling data should be performed by an experienced health and safety professional.

General Information

The significance of mold detected in indoor air can be determined by comparing both concentrations and types of organisms found in indoor and outdoor air samples. In non-problem environments, the concentrations of mold species in indoor air typically are similar to, or lower than, the concentrations seen in outdoor air. When air concentrations indoors are consistently higher than concentrations outdoors, then indoor sources may be indicated. Species of mold found in indoor and outdoor air typically are similar if outdoor air is the primary source for the mold. Knowledge of the types of mold normally found in indoor and outdoor environments is required to assess the significance of such findings. The American Conference of Governmental Industrial Hygienists (ACGIH) emphasizes that active mold growth in indoor environments is inappropriate and may lead to adverse health effects. Many molds produce allergens, and some produce toxins. Environmental sources of some common airborne mold allergens include outdoor air, settled dust, indoor growth, and humidifiers.

4.2 CORRECTIVE ACTION

The goal of corrective action is to remove or clean damaged materials in a way that prevents the emission of mold and dust contaminated with fungi from leaving a work area and entering an occupied or non-abatement area, while protecting the health of workers performing the abatement.

Thus, there are two basic components of the corrective action program

1. Cleaning (or removing) the affected areas/materials.

2. Ensuring that during the cleaning/removal activity, there is no contamination/spread of the microbes to non-affected areas.

4.2.1 Cleaning/Removal of the Affected Areas/Materials

The manner in which cleaning the affected areas/materials is accomplished varies depending on the materials impacted as follows:

Material Impacted Cleaning Method

Non-porous (e.g., metals, glass, and hard plastics) and semi-porous (e.g., wood, and concrete) materials If structurally sound and has visible growth can be cleaned and reused. Cleaning should be done using a detergent solution.

Porous materials (e.g., fabrics) Should be discarded if possible, but may be able to be cleaned if necessary.

Cleaning may include HEPA vacuuming followed by extraction cleaning, i.e., steam cleaning with an approved disinfectant.

4.2.2 Preventing Spread of Contamination during Cleaning

Equally important as proper cleaning of the area/materials is the prevention of the spread of contamination to other areas. Recommended protocols are based on the size of the area impacted, and whether the HVAC system has been impacted.

4.2.2.1 HVAC System Not Affected

If through visual inspection or sampling it has been determined that the HVAC system has not been impacted by microbial growth, the protocols for ensuring there is no cross-contamination depend on the size of the area impacted. Table 2 presents the guidelines for corrective action in situations where the HVAC system is not affected.

4.2.2.2 HVAC System Affected

If through visual inspection or sampling it has been determined that the HVAC system has been impacted by microbial growth, the protocols for ensuring there is no cross-contamination are somewhat more extensive. The extent of activities required again depends on the size of the area impacted. Table 3 presents guidelines for corrective action in situations where the HVAC system is impacted.

4.2.2.3 Completion of Corrective Action

Refer to Appendix C for a decision tree to assist with determining when corrective action is

Complete.

Table 2

Preventing Spread of Contamination if HVAC System Not Affected

Size of impacted area	Who can perform	PPE1	Work area controls	Completion activities
Small Isolated Area of Impact (< 10ft 2)	Regular Building Maintenance Personnel With Proper Training Training should Include OSHA Hazcom & address: - Proper clean up - Personal protection - Potential health Hazards	**Respiratory Protection (e.g., N95 Disposable Respirator)** Gloves & Eye Protection	Work area should be unoccupied Vacating people from adjacent spaces not Necessary2 Containment of the work area not necessary Dust Suppression such as misting (not soaking) surfaces prior to work with a dilute detergent solution recommended	Contaminated materials that cannot be cleaned should be sealed in a plastic bag & removed from the building. Disposal can be with general refuse. Work area used by workers should be cleaned with a damp cloth and/or mop and a detergent solution. All areas should be left dry and visibly free from contamination & debris.
Mid-Sized Area of Impact (10-30ft2)	Same	Same	As above for small areas plus work area floor should be covered with a plastic sheet and sealed with tape to contain dust/debris	As above for small areas plus work area used by workers for egress should also be HEPA vacuumed prior to cleaning with damp cloth/mop.
Large Isolated Area (30-100ft 2) e.g., several wallboard panels Note: If work expected to generate a lot of dust or microbial growth heavy3 then handle as Extensive Contamination	A health and Safety professional with experience in microbial corrective action should be consulted prior to work. Workers should be trained as above and in the handling of hazardous materials	Same	Work area and adjacent areas should be unoccupied Work area floor and adjacent areas should be covered with plastic & sealed Seal ventilation ducts/grills in the work area and adjacent areas with plastic If possible isolate HVAC system or shut off Same dust suppression techniques	Same as above mid-sized area
Extensive Contamination (> 100 contiguous ft2)	Same as above for large area	Full face respirators with N100 cartridges Disposable full body protection	Same as above for large area plus work area must be subject to negative pressure (exhaust fan with HEPA filter) and provided air locks and a decontamination room	Same as above for mid-sized area plus: Wipe bags of contaminated material in decontamination chamber prior to removal with damp cloth with detergent or HEPA vacuum. Air samples should be taken prior to re-occupation

1 Personal Protection Equipment

2 Unless infants present, persons recovering from recent surgery, immune suppressed persons, or people with chronic inflammatory lung disease (e.g., asthma, hypersensitivity pneumonitis, and severe allergies)

3 Heavy microbial growth means “blanket coverage” vs. patchy growth. Excessive dust could be generated from abrasive cleaning of contaminated surfaces, demolition of plaster walls

Table 3

Preventing Spread of Contamination if HVAC System Affected

Size of impacted area	Who can perform	PPE1	Work area controls	Completion activities
Small isolated area(<10ft2) in the HVAC system	Regular Building Maintenance Personnel With Proper Training Training should include OSHA Hazcom & address: Proper clean up Personal protection - Potential health hazards	Respiratory Protection (e.g., N95 Disposable Respirator) Gloves & Eye Protection	Work area should be unoccupied HVAC system should be shut down Work Area Floor should be covered with a plastic sheet & sealed with tape to contain dust/debris Dust Suppression such as misting (not soaking) surfaces prior to work with a dilute detergent solution recommended	Growth supporting materials that area contaminated, such as the paper on the insulation of interior lined ducts should be removed & sealed in plastic bags. Other contaminated materials that cannot be cleaned should be sealed in a plastic bag & removed from the building. Disposal can be with general refuse. The work area and areas immediately surrounding the work area should be HEPA vacuumed and cleaned with a damp cloth and/or mop and a detergent solution. All areas should be left dry and visibly free from contamination & debris. A variety of biocides are recommended by HVAC manufacturers for use with HVAC components, such as cooling coils & condensation pans. Contact HVAC manufacturer for recommendations.
Greater than 10ft2 In HVAC System	A health and safety professional with experience in microbial corrective action should be consulted prior to work. Workers should be trained as above & in the handling of	Respiratory Protection (e.g., N95 Disposable Respirator) unless area of impact > 30ft2, then full face respirators with N100 cartridges required	Same as above plus: Complete isolation of work area from other areas of the HVAC system using plastic sheeting sealed with duct tape Work area must be subject to negative pressure (exhaust fan with HEPA filter) and provide air locks and a decontamination	Same as above for mid-sized area plus - Air sampling should be conducted prior to re-occupancy with the HVAC system in operation to determine if the area(s) served by the system are fit to reoccupy - The involvement of an HVAC design engineer should be considered if problems such as incorrect system pressurization or

	hazardous materials	Disposable full body protection	room if contamination area > 30ft2	oversized coils exist.

Personal Protection Equipment

2 Unless infants present, persons recovering from recent surgery, immune suppressed persons, or people with chronic inflammatory lung disease (e.g., asthma, hypersensitivity pneumonitis, and severe allergies)

APPENDIX A

MOLD PREVENTION

AND

CONTROL

FACT SHEET

MOLD PREVENTION AND CONTROL

Molds (also referred to generically as “microbes”) are found in all environments, indoors and outdoors, in homes, hospitals, and workplaces. Molds live in soil, on plants, and on dead and decaying organic matter. Molds spread by releasing spores, and they then usually settle onto surfaces of all types. “Mildew” is a general term for various species of mold that commonly grows on fabrics, windowsills, bathroom, tiles, etc. Another familiar type of mold is Penicillium, from which the widely used antibiotic penicillin is made.

Molds need both food and moisture to survive; since molds can digest most organic materials, water is the factor that limits mold growth. Molds will often grow in damp or wet areas indoors. Common sources of water or moisture problems include roof leaks, localized flooding caused by plumbing failures or heavy rains, areas where moisture condenses and near leaking plumbing fixtures or lines. Uncontrolled humidity can also be a source of moisture leading to mold growth, particularly in hot, humid climates.

Concern about indoor exposure to mold has been increasing as the public becomes aware that exposure to mold may cause health effects and various allergy symptoms.

Health Concerns

Mold spores can be airborne, and get indoors through doors, the ventilation system or be carried in from outside on shoes and clothing. As a general rule of thumb, in a “healthy” building the concentration and the mix of mold species tend to be similar to the outdoor environment. When moisture problems occur and mold growth results, building occupants may begin to report odors or a variety of health concerns, such as headaches, breathing difficulties, skin irritations, allergic reactions, and aggravation of asthma symptoms; all of these symptoms could potentially be associated with mold exposure. Although there is evidence documenting severe health effects of molds in humans, most of this evidence is derived from ingestion of contaminated foods or occupational exposures in agricultural settings where inhalation exposures can be very high. Molds produce allergens, irritants, and in some cases, toxins that may cause reactions in humans. The presence of mold in a building does not necessarily mean that toxins are present or that they are present in large quantities. The types and severity of symptoms depend, in part, on the types of mold present, the extent of an individual’s exposure, an individual’s age, and their existing sensitivities or allergies.

Some of the more common molds found indoors and outdoors throughout the United States are Aspergillus, Penicillium, Alternaria and Cladosporium. Only a small group of molds have been associated with infectious disease. Stachybotrys atra (chart arum) is a type of mold that has caught the public’s attention in recent years. Some strains of Stachybotrys atra can produce toxins under certain conditions.

Although some toxins are known to affect humans, for many toxins little information is available. Preliminary reports from an investigation of an outbreak of illness in children suggested an association between the illness and Stachybotrys atra. However, review of the evidence of this association by the Center for Disease Control (CDC) resulted in a published clarification stating that such an association was not established.

Prevention

The key to mold control is moisture control. All moisture problems must be controlled before it becomes a source for mold growth. Mold prevention tips include:

- Fix leaking plumbing and leaks in the building envelope
- Control moisture caused by condensation
- Maintain low indoor humidity, below 60%
- Clean and dry, wet, or damp spots within 48 hours

Remediation

The presence of mold and water damage should be addressed immediately. In all instances, any source of standing water or moisture must be stopped and the extent of water damaged determined. Water damaged materials should be dried and repaired or replaced. Any source of a sewage leak must be corrected immediately and properly cleaned. All mold or contaminated materials should be remediated by properly qualified individuals and following recommended guidelines.

Other References:

EPA guidance document Mold Remediation in Schools and Commercial Buildings New York City Department of Health Guidelines on Assessment and Remediation of Fungi in Indoor Environments

APPENDIX B

MOLD GROWTH

PREVENTION

CHECKLIST

Mold Growth Prevention Checklist

Building:_____ Inspector:_____

Floor/Wing:_____ Date:_____

Room/Area"_____

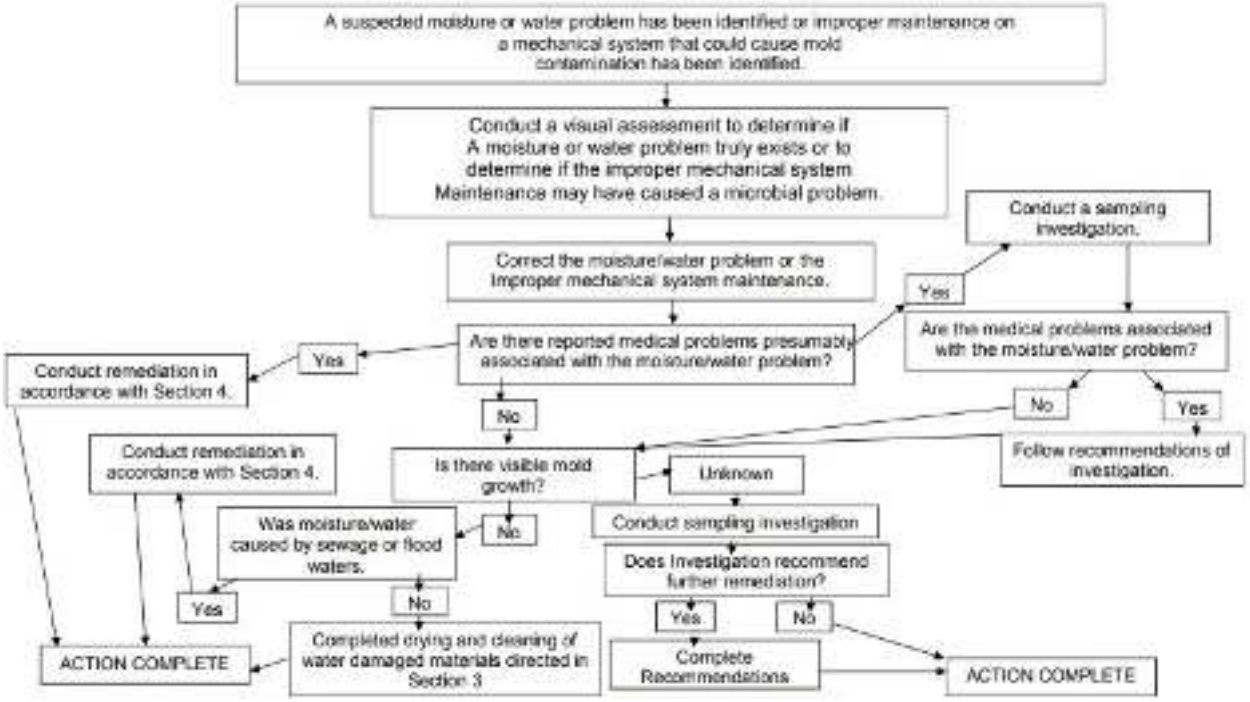
Condition	Condition noted? (Yes/No)	Actions taken
Roof Leaks:		
1. Leaks at roof penetration		
2. Leaks at roof drains		
3. Leaks at flashing		

Moisture through building envelope:		
1. Seam sealant leaking		
2. Moisture wicking into interior finishes		
Foundation:		
1. Surface water draining towards foundation		
2. Surface water collecting in crawlspace or basement		
Wall systems:		
1. Condensation in chases		
2. Water staining on walls		
3. Water staining on walls at drinking fountains		
4. Water staining of wall coverings, i.e., vinyl wall covering		
Floor systems:		
1. Water staining of floor coverings		
2. Water damage to wood floor		
HVAC Systems:		
1. Filters in good condition		
2. Condensation on interior of ductwork		
3. Condensation on exterior of ductwork		
4. Condensation drip pans drains clogged		
Cooling towers:		
1. Proper water treatment		
2. Frequency of water treatment		
3. Type of water treatment		
Recirculated water systems:		
1. Proper water treatment		
2. Frequency of water treatment		
3. Type of water treatment		
Sewer systems:		
1. Evidence of leaks		
2. Evidence of leaks at toilet wax ring		
3. Ejector pump operating properly		
Domestic water system:		
1. Evidence of leaks		
2. Evidence of condensation on exterior of piping		
Food preparation and/or serving area:		
1. Condensation on ceilings or walls		
2. Water damage to floor coverings		
3. Water damage to walls		

APPENDIX C

MOLD PLAN

DECISION TREE



V. REFERENCES

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Performance Improvement Program Policy	Policy #	PO4006
Responsible	Facilities	Revised/Reviewed	1/23/2023

I. PURPOSE

It is the policy of Watsonville Community Hospital to implement and maintain an active Performance Monitoring program that may include each of the Environment of Care areas. The results of monitoring these indicators are reported to the Safety or Environment of Care Committee on a scheduled basis.

II. POLICY

1. The Performance Improvement Program may focus on five key areas of performance:
    a. Patient/member satisfaction - patient/member's perception that his needs are being handled in a timely and efficacious manner. (Hospital Survey Card).
    b. Medical Center staff satisfaction - staff perception that they are receiving support and services in a timely and efficacious manner (Administrative Report).
    c. Productivity/effectiveness - the department's own evaluation of its work output.
    d. Management and staff development - type and amount of in-service and continuing education provided. (Department Education Survey - Criteria Base Job Description).
    e. Department safety - evidence that department safety programs have been effective.
    f. Equipment or Environment Reports.
2. The Director of Facilities/Plant Operations. will determine, for each performance area, specific performance indicators to be monitored. The Director may add, delete, or change those indicators, as necessary, to assure productive monitoring. Performance indicators will be monitored continuously.
3. The Director of Facilities/Plant Operations. or designated representative, on a monthly basis, will review the monitoring results of the previous month and establish corrective action.
4. The Director of Facilities/Plant Operations. on a monthly basis, will analyze the monitoring results, identify significant trends and institute corrective action as required.
5. Once each quarter, the Director of Facilities/Plant Operations. will prepare a report summarizing the results of monitoring activities and identifying significant trends, corrective actions taken and problem status. This report will be sent to the P.I. Committee for review.

Note: Compile data to provide the tending information required in identifying potential problems requiring corrective action.

III. DEFINITIONS

N/A

IV. PROCEDURE

N/A

V. REFERENCES

ENVIRONMENT OF CARE MANUAL

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	General Safety Policy	Policy #	PO4007
Responsible	Facilities	Revised/Reviewed	1/17/2023

I. PURPOSE

To define the general safety rules for work in the Plant Operations Department.

II. POLICY

1. Work areas
    a. Keep all machinery and shop areas in a clean, orderly and well organized condition.
    b. Allow sufficient space around machinery to permit inspection and repair.
    c. Provide at least 50-foot candles of lighting in all work areas.
    d. Install tube guards over lights that are less than eight feet from the floor, or which may be subject to damage during the movement of large boxes or equipment.
    e. Isolate and barricade work areas from external hazards or distractions.
    f. Post warning signs around work areas so that they do not pose a hazard to others.
    g. Do not leave tools or equipment where they may create a tripping hazard.
    h. Keep all fire exits clear and do not obstruct identifying signs.
    i. Make sure all work areas are properly ventilated for the work being performed.
2. Machinery and Equipment (ALL SAFETY DEVICES MUST BE IN PLACE).
    a. Operate only that machinery or equipment which you have been trained and authorized to use.
    b. Do not use equipment with frayed cords or broken plugs.
    c. Inspect ropes, cables, and chains for defects regularly and replace them as necessary.
    d. Make certain machine guards are properly attached or installed as required
3. Hazardous substances
    a. Use eye protection whenever indicated or required.
    b. Use other types of protective devices, equipment or clothing whenever indicated or required.
    c. Store flammable liquids in limited quantities in containers approved for such use.
    d. Make certain containers are properly marked. Discard substances left in unmarked or improperly marked containers.
    e. Use the proper trigger assembly for the delivery of compressed air used in cleaning so that the pressure does not exceed 30 PSI. Do not clean clothing with compressed air.
    f. If accidentally exposed to a toxic substance, obtain medical attention immediately.
    g. Remove broken glass immediately with a broom or brush and dustpan. Do not pick up broken glass by hand. Do not enter the rooms of patients receiving radioisotopes until authorized to do so by a nuclear medicine physician or technician. When authorized to enter, wear a film badge (issued by the department administrator of Radiology or Nuclear Medicine) and wear any protective attire indicated by the nursing staff or staff of Radiology or Nuclear Medicine.
    h. Know the location of the Safety Data Sheets, review the sheet on each new product before using the product and review the entire collection of SDS annually.
4. Ladders
    a. Check to be certain all elevated platforms, step or extension ladders are in good repair before use.
    b. Use only ladders with a non-slip base.
    c. Do not use metal ladders for electrical work of any kind.
5. Other Precautions:
    a. Use proper lifting techniques at all times. Use mechanical equipment or request assistance when lifting very heavy objects.

   b. Do not participate in horseplay or practical jokes on the work site.
6. Report any and all accidents to the supervisor immediately. Obtain medical treatment as necessary and submit required documentation promptly.
7. Lock-Out/Tag-Out Policy will be followed in regard to Securing Energy Sources.

III. DEFINITIONS
N/A

IV. PROCEDURE

V. REFERENCES
OSHA CFR 29

VI. STAKEHOLDERS
Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Arc Flash Prevention Policy	Policy #	PO4008
Responsible	Facilities	Revised/Reviewed	1/23/2023

I. PURPOSE

The purpose of this policy is to prevent accidental injury caused by an arc flash event and to promote safe facility practices among employees. This policy is intended to comply with OSHA 29 CFR Part 1910, Subpart S, and NFPA 70E.

II. POLICY

Arc flash is a short circuit that flashes from one exposed live conductor to another, or to ground. The resulting ionized air creates electrically conductive super-heated plasma that can reach temperatures of 5000°F and above. The explosion takes less than one second and produces a brilliant flash, intense heat, and a pressure blast equivalent to several sticks of dynamite. Since the vast majority of events (>80%) are caused by human error, there is a high risk that one or more people will be in the flash zone. Without adequate PPE, the risk of serious injury or death is high.

III. DEFINITIONS

- **Arc Flash Hazard-** A dangerous condition associated with the possible release of energy caused by an electric arc.
- **Arc Flash Hazard Analysis**- A study investigating a worker's potential exposure to arcflash energy, conducted for the purpose of injury prevention and the determination of safe work practices, arc flash protection boundary, and the appropriate levels of PPE.
- **Boundary, Arc Flash Protection**- When an arc flash hazard exists, an approach limit at a distance from a prospective arc source within which a person could receive a second degree burn if an electrical arc flash were to occur.
- **Boundary, Limited Approach**- An approach limit at a distance from an exposed energized electrical conductor or circuit part within which a shock hazard exists.
- **Boundary, Prohibited Approach**- An approach limit at a distance from an exposed energized electrical conductor or circuit part within which work is considered the same as making contact with the electrical conductor or circuit part.
- **Boundary, Restricted Approach**- An approach limit at a distance from an exposed energized electrical conductor or circuit part within which there is an increased risk of shock, due to electrical arc over combined with inadvertent movement, for personnel working in close proximity to the energized electrical conductor or circuit part.
- **De-energized**- Free from any electrical connection to a source of potential difference and from electrical charge; not having a potential different from that of the earth.
- **Electrically Safe Work Condition-** A state in which an electrical conductor or circuit part has been disconnected from energized parts, locked/tagged in accordance with established standards, tested to ensure the absence of voltage, and grounded if determined necessary.
- **Qualified Person**- One who has skills and knowledge related to the construction and operation of the electrical equipment and installations and has received safety training to recognize and avoid the hazards involved.
- **Single-Line Diagram**- A diagram that shows, by means of single lines and graphic symbols, the course of an electric circuit or system of circuits and the component devices or parts used in the circuit or system.
- **Ungrounded**- Not connected to ground or to a conductive body that extends the ground connection.
- **Unqualified Person**- A person who is not a qualified person.

IV. PROCEDURE

1. Facility Safety Officer
    a. Assure implementation of this policy.
2. Director of Facilities Management
    a. Oversee completion of Arc Flash Analysis and implementation of arc flash hazard remediation.
    b. Assure the proper placement of Arc Flash hazard labels.
    c. Assist personnel in implementing the provisions of this program.
    d. Ensure employees receive training appropriate to their assigned electrical tasks and maintain documentation of such training.
    e. Ensure employees are provided with and use appropriate protective equipment.
    f. Ensure employees comply with all provisions of the Arc Flash Safety Program.
    g. Evaluate overall effectiveness of the Arc Flash Safety Program on a periodic basis.
3. Employees
    a. Follow the work practices described in this document, including the use of appropriate protective equipment and tools.
    b. Attend all training required relative to this program.
    c. Immediately report any concerns related to electrical safety to supervision.

Implementation of this policy requires:

- Completion of Arc Flash analysis surveys.
- Labeling electrical switches, bus locations, and panel boards with appropriate warning labels.
- Training qualified employees on safe work practice and personal protective equipment (PPE) requirements.
- Acquisition of necessary PPE based upon the arc flash survey

Completion of Arc Flash Surveys

This is an analysis performed on your facility. The analysis involves a detailed field verification of your electrical distribution system from your utility to the equipment on the floor. The analysis is conducted by qualified engineers utilizing software specifically designed to perform the calculations of the arc flash hazard levels. Hazard levels in most cases can be reduced by simple, cost-effective modifications.

Labeling

Analyzed electrical panels, disconnects, and bus locations are labeled to indicate hazard boundaries and required PPE needed to safely work on the circuit.

Training

Employees who are exposed to an electrical hazard that is not reduced to a safe level by the installation must be trained. The level of electrical safety training provided is dependent on whether the employee is classified as a “qualified person” or “unqualified person”. A "qualified person" shall be trained and knowledgeable in all the following topics:

- Arc Flash program PPE requirements, what PPE must be worn, when, and by whom.
- Construction and operation of equipment on which work is assigned.
- Skills and techniques necessary to distinguish exposed energized parts from other parts of electrical equipment.
- Skills and techniques necessary to determine the nominal voltage of exposed live parts.
- The approach distances specified in this document and the corresponding voltages to which the qualified employee will be exposed.
- The process necessary to determine the degree and extent of electrical hazards along with the PPE and job planning necessary to perform the task safely.

- A person can be considered qualified with respect to certain equipment and methods but unqualified for others.
- An "unqualified person" shall be trained in the inherent hazards of electricity and any related work practices that are necessary for their safety.
- Training must be provided before the employee is assigned duties that involve work near or on electrical systems.
- Each Director of Plant Operations shall maintain a record of all electrical training provided to their employees along with a listing of all employees classified as qualified persons.

Proper Personal Protective Equipment

PPE shall be worn when any work is conducted within the arc flash zone for specific equipment.

Note: The primary method of protecting employees from arc flash as spelled out in 70E is de-energizing live parts prior to working on or near them using proper lockout-tagout procedures. This limits the employee's exposure to electrical hazards during the shutdown and verification process. Many believe they don't have to worry about arc flash because they have instituted a "no live work" policy at their facility. Because the employee is still exposed during shutdown and verification, this policy does nothing to remove the need to protect against arc flash. Until you have verified that the circuit is de-energized, it must be treated as energized and the appropriate Personal Protective Equipment (PPE) must be used to protect against arc flash.

Flame retardant (FR) clothing shall be in compliance with the following NFPA 70E Table.

Category	Cal/cm2	Required Clothing
0	1.2	Untreated cotton
1	5	Flame retardant (FR) shirt & FR pants
2	8	Cotton underwear, FR shirt, and FR pants
3	28	Cotton underwear, FR shirt, and FR pants; and FR coverall
4	40	Cotton underwear, FR shirt, FR pants, and double-layer switching coat and pants

- FR eye protection and FR hearing protection shall be worn as part of the PPE requirement for arc flash safety.
- Employees working in areas where electrical hazards are present shall be provided with, and shall use, protective equipment (Arc Flash Gear) that is designed and constructed for the specific body part to be protected and for the work to be performed.
- Protective equipment (Arc Flash Gear) required by this program is to be provided at no cost to employees. Such equipment shall include an Arc Flash rated apparel, eye protection, head protection, hand protection, insulated footwear, and face shields where necessary.
- All protective equipment shall be maintained in a safe, reliable condition by the employee to whom it is issued.
- Employees shall wear nonconductive head protection whenever there is a danger of a head injury from electric shock or burns due to contact with live parts or from flying objects resulting from an electrical explosion.
- Employees shall wear nonconductive protection for the face, neck, and chin whenever there is danger of injury from exposure to electric arcs or flashes or from flying objects resulting from an electrical explosion.
- Employees shall wear protective equipment for the eyes and face whenever there is a danger of injury from electric arcs, flashes, or from flying objects resulting from an electrical explosion.
- Employees shall wear rubber-insulating gloves where there is a danger of hand and arm injury due to contact with live parts or possible exposure to arc flash burn.
- If an employee is wearing shoes other than hard-soled type (tennis shoes are not considered hard soled), he/she must wear dielectric overshoes.
- Face shields without an arc rating will not be used for electrical work. Safety glasses or goggles must always be worn underneath face shields.

- Personal protective equipment shall be provided to and used by all employees working within the Flash Protection Boundary.
- FR apparel shall be visually inspected before each use. FR apparel that is contaminated or damaged shall not be used. Protective items that become contaminated with grease, oil, flammable liquids, or combustible liquids shall not be used.
- The garment manufacturer's instructions for care and maintenance of FR apparel shall be followed.
- When FR apparel is worn to protect an employee, it shall cover all ignitable clothing and allow for movement and visibility.
- FR apparel must cover potentially exposed areas as completely as possible. FR shirtsleeves must be fastened and FR shirts/jackets must be closed at the neck.
- Non-melting, flammable garments (i.e., cotton, wool, rayon, silk, or blends of these materials) may be used as under layers beneath FR apparel.
- Meltable fibers such as acetate, nylon, polyester, polypropylene, and spandex shall not be permitted in fabric under layers next to the skin. (An incidental amount of elastic used on non-melting fabric underwear or sock shall be permitted.)
- FR garments worn as outer layers over FR apparel (i.e., jackets or rainwear) must also be made from FR material.
- Flash suits must permit easy and rapid removal by the user.

Contract Employees

Safety programs used by contractors on facility jobsites must meet or exceed all applicable guidelines of this policy.

V. REFERENCES

Human Resources Policy and Procedure Manual

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Lockout Tag-out Policy	Policy #	PO4009
Responsible	Facilities	Revised/Reviewed	1/23/2023

I. PURPOSE

This procedure establishes the minimum requirements for the lockout of mechanical/electrical energy sources when maintaining, servicing or modifying equipment and systems. It will ensure that the equipment or system is:

Stopped and isolated from all potentially hazardous energy sources, locked out and tested before individuals perform any activities where the unexpected start-up of the machine or equipment of stored energy could cause injury.

II. POLICY

It is the policy of Watsonville Community Hospital that all personnel are required to comply with lockout/tag-out procedures. Only specifically authorized employees shall perform lockout/tag-out functions and only in accordance with this procedure. No attempt shall be made to start, energize or use machines or equipment that has been locked out or tagged out for service or maintenance. Failure to utilize lockout/tag-out procedures or to violate any such procedure that is in effect will be viewed as a serious breach of safety policy.

III. DEFINITIONS

N/A

IV. PROCEDURE

All Watsonville Community Hospital personnel, vendors and contractors are required to comply with lockout/tag out procedures.

EXEMPTIONS

Exemptions to this procedure which are allowed by OSHA standard (Appendix A) are as follows:

1. Work on cord and plug-connected electrical equipment for which exposure to the hazards of unexpected energizing or start-up of the equipment is controlled by the unplugging of the equipment from the energy source. The cord cap must be tagged with a signed and dated danger tag and the cord must be under the exclusive control of the person performing the servicing or maintenance.
2. Hot tap operations involving electrical and distribution systems for substances such as gas, steam, water or petroleum products when they are performed on pressurized pipelines, provided that it can be shown that:
    a. Continuity of service is essential
    b. Shutdown of the system is impractical
    c. Documented procedures are followed, and special equipment is use which will
    d. provide proven, effective, protection for personnel.
    e. d. The procedure has been reviewed and approved by _____.

V. REFERENCES

OSHA 29CFR 1910

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Orientation of New Employees Policy	Policy #	PO5000
Responsible	Facilities	Revised/Reviewed	1/23/2023

I. PURPOSE

Define a policy for the orientation of new employees.

II. POLICY

All new hospital employees receive an orientation to the hospital. The orientation, which is conducted by the Human Resources Department within 15 days of the employee's starting date, addresses organizational structure, hospital policies applying to all employee benefits, services available to employees, safety, infection control and the physical layout of the hospital.

1. Each new employee will receive an orientation to the Plant Operations Department from the Director of Facilities/Plant Operations or designated representative before assuming his duties. This orientation will be documented and will be made part of the employee's file within the department.

2. Employees also receive departmental safety orientation at their respective work areas regarding hazards and their responsibilities to patients, visitors, and co-workers before assuming his or her duties. In addition, all staff participate in periodic refresher training in their departments relative to the Environment of Care. This orientation will also be documented and made part of the employee's personnel file.

3. Employees receive ongoing education annually relative to the environment of care. Competency of education is assessed and documented.

4. Initial and ongoing education programs include describing and demonstrating methods for reducing and eliminating risks in the Environment of Care, actions to take in the event of an environment of care incident, and how to report environment of care risks.

NEW EMPLOYEE DEPARTMENT ORIENTATION

Employee's Name: _____ Orientation Date: _____

Introductory Period

_____ Rate of Pay
_____ Work Schedule
_____ Break and Meal Periods
_____ Hospital Attendance Program
_____ Sickness or Tardiness Call-In Procedure
_____ Vacation Eligibility; Requests
_____ Timecards
_____ Pay Practices
_____ Sick Leave
_____ Holidays
_____ Vacation
_____ Notification of Employee Address or Telephone Change
_____ Safety Awareness; Accident Prevention
_____ Security

Work Area Orientation

____ Department Chain-of-Command
____ Duties and Responsibilities of the Position
____ Standards of Performance
____ Criteria-based Evaluation
____ Department Policies and Procedures
____ Emergency Preparedness Plan
____ Fire Plan
____ Department Layout, including:
____ Location of fire extinguishers and alarms
____ Location of exits to the outside
____ Location of hazardous material lists and Safety Data Sheets

_____ _____

Employee Signature Supervisor

III. DEFINITIONS
N/A

IV. PROCEDURE
N/A

V. REFERENCES
Human Resources Manual
The Joint Commission EC.01.01.01.3

VI. STAKEHOLDERS
Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	In-service Education Policy	Policy #	PO5001
Responsible	Facilities	Revised/Reviewed	1/23/2023

I. PURPOSE

To outline the in-service education program for the Facilities/Plant Operations department.

II. POLICY

1. All new employees shall receive in-service education prior to assuming their job duties.
    a. Such in-service training shall include, as appropriate to each employee's assigned duties:
        i. The handling of hazardous materials used in the maintenance department.
        ii. Maintenance and operation of:
            1. the electrical distribution system,
            2. the emergency generators,
            3. the elevators, lifts
            4. the HVAC system,
            5. the plumbing and water distribution systems,
            6. the boiler systems,
            7. the medical-gas system,
            8. the medical/surgical vacuum system,
            9. the fire alarm system and
            10. the communications system
        iii. Job safety techniques such as:
            1. Lockout/tagout procedure,
            2. Handling of medical-gas cylinders, and
        iv. Emergency Response
            1. Emergency Operations Plan
            2. Fire Plan
            3. Hazard spill response
            4. Equipment failure response
2. Additional in-service education will be given to all employees when appropriate, as determined by the Director of Facilities/Plant Operations.
    a. As a result of their review of personnel evaluations, equipment maintenance histories and work-related accidents or injuries,
    b. To acquaint personnel to the handling, operation, and maintenance of new equipment, or
    c. To inform personnel about new or modified government regulations that relate directly to them or their job duties.
3. In-service education shall be documented and filed in the Plant Operations department.

III. DEFINITIONS

N/A

IV. PROCEDURE

N/A

V. REFERENCES

The Joint Commission, EC.01.01.01.3

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Continuing Education	Policy #	PO5002
Responsible	Facilities	Revised/Reviewed	1/25/2023

I. PURPOSE

To define the procedure by which eligible employees may receive continuing education.

II. POLICY

1. Plant Operations staff shall be encouraged to take advantage of relevant continuing education.
2. The department will make available to the employees, information received concerning educational programs.
3. Supervisors will provide guidance to employees, as requested, concerning the selection of programs that will help employees achieve their performance or advancement goals.
4. An effort will be made to adjust staffing schedules to accommodate the needs of employees participating in continuing education programs.

III. DEFINITIONS

N/A

IV. PROCEDURE

Instruction is provided within the organization or from external sources which enables the individual to build upon previously acquired skills, develop new skills to enhance growth and/or acquire current knowledge in his/her profession or occupation.

V. REFERENCES

Human Resources Policy and Procedure Manual

VI. STAKEHOLDERS

Facilities

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Release of Specimens to Law Enforcement Agencies	Policy #	LAB1838
Responsible	Director of Laboratory	Revised/Reviewed	10/18/2022~~10/23/2020~~

I. PURPOSE

A. To provide timely release of specimens to law enforcement agencies.
B. To provide an audit trail of specimens released to law enforcement agencies.

II. POLICY

In accidents or deaths under the jurisdiction of law enforcement agencies, laboratory specimens may be subject to subpoena. In an effort to facilitate cooperation between Watsonville Community Hospital and these agencies, and to provide timely release of specimens, laboratory specimens (blood, urine and other body fluids) will be released to identifiable law enforcement personnel upon the verbal request of law enforcement agencies.

III. DEFINITIONS

N/A

IV. PROCEDURE

1. A representative from a local or state law enforcement agency will make a verbal request to laboratory staff to obtain specimens from a specific patient or patients. These agencies include but are not limited to: Santa Cruz County Sheriff Coroner's Office, Monterey County Sheriff Coroner's Office and the California Highway Patrol.
2. The request may be for specific specimens or for all specimens submitted to the lab.
3. A CLS may be consulted to identify the most appropriate specimen(s) for specific purposes. For example, if a urine specimen is requested, but is QNS for additional toxicology testing, the technologist may suggest that an EDTA tube drawn at the same time would be useful.
4. The specimen(s) will be packaged in a sealed biohazard bag for transportation.
5. The requesting officer must show a badge or other identifying document to obtain the specimen(s). A driver's license is not acceptable; the document must clearly show that the individual is a member of the law enforcement agency.
6. The requesting officer should provide his/her business card and indicate on the back of the card the name of the patient whose specimens have been requisitioned and the date of transfer to law enforcement custody.
7. The requesting officer must sign the form, "Release of Specimen to Law Enforcement Agency". CLS or Lab Management should fill out remainder of form and affix a patient label to the form.
8. The business card and release form will be given to the Lab Manager.
9. The Laboratory Manager or designee will enter an LIS specimen comment for the appropriate order indicating that the specimen(s) was released to a duly identified law enforcement officer according to this policy. The officer's name, agency affiliation and date of release will be indicated.

10. If any instance arises after hours which is ambiguous or unclear, CLS in charge should attempt to seek guidance from the following in the order listed:
    a. Lab Manager
    b. Pathologist on call
    c. Administrator on call

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Packing and Shipping Infectious Substances	Policy #	LAB0001
Responsible	Laboratory Director	Revised/Reviewed	10/18/2022~~10/2020~~

I. PURPOSE

This document includes guidelines that are applicable to the transport of infectious substances and diagnostic specimens. Also, it provides information for identifying and classifying the material to be transported and for its safe packaging and transport. The godliness stress the importance of developing working relationships between the groups involved –the sender, the carrier and the receiver- in order to provide the safe and expeditious transport of this material. Postal, airline and other transport industry personnel holds concern about the possibility of their becoming infected as a result of exposure to infectious microorganisms that may escape from broken, leaking or improperly packaged material. The packaging of infectious materials for transport must therefore address these concerns and be designed to minimize the potential for damage during transport. In addition, the packaging will serve to ensure the integrity of the materials and timely processing of specimens (WHO).

II. POLICY

The requirements and regulations governing the transport of infectious substances change frequently. Shippers are responsible for being aware of these changes, adhering to current regulations, and interpreting applicable regulations for themselves and their facilities.

III. DEFINITIONS

A. Infectious Substances:
An infectious substance is defined as a substance contain a viable microorganism, such as a bacterium, virus, rickettsia, parasite or fungus, that is known or reasonably believed to cause disease in humans or animals (WHO).

B. Diagnostic Specimens:
A diagnostic specimen is defined as any human or animal including, but not limited to, excreta, blood and its components, tissue and tissue fluids collected for the purposes of diagnosis, but excluding live infected animals (WHO).

IV. PROCEDURE

Governing Authorities and Regulations:

A. Origin of Regulations
Most regulations for the air transport of dangerous goods throughout the world originate as decisions made by the UN committee of Experts. The International Civil Aviation Organization (ICAO) uses these regulations to develop formal and standardized Technical Instructions for the safe transportation of Dangerous Goods by air. In the United States, the Department of Transportation (DOT) regulates the commercial transportation of Dangerous Goods by both air and ground carriers. Just as the International Air Transport Association (IATA) derives its requirements from the ICAO, the DOT also derives its regulations form the ICAO. For practical purposes, shippers of infectious substances can consider compliance with IATA requirements to compliance with DOT regulations.

B. Importance of regulations
Laboratory workers who ship or transport dangerous goods, in general, and infectious substances in particular, by the commercial ground or air carrier are required to follow set off national or

international requirements and regulations. The purpose of these regulations is to protect the public, emergency responders, laboratory workers, and personnel in transportation industry from accidental exposure to the contents of the packages. Also, to minimize the potential risk of damaging the content of the package during transport and to reduce the exposure of the shipper to the risks of criminal and civil liability associated with the improper shipment of dangerous goods.

C. Effectiveness of Regulations
According to World Health Organization (WHO), there are no recorded cases of illness attributable to the release of specimens during transport, although there are reported incidents of damage to the outer packaging of properly packaged materials (Who). This statement and also the statistical records show that the regulations are extremely effective in protecting both the content and the persons who handle the packages.

D. Exceptions
The transportation of non-category A substances is exempt from most DOT regulations if the specimen are transported by private or contract courier in motor vehicle used exclusively to transport such substances. Such substances are however required to be kept in leak-proof containers, securely sealed during transportation.

E. Specific Regulations
IATA and DOT regulations mandate the minimum standards for packing infectious substances that can cause disease in humans, or animals. The safe and legal transport of these substances is based on the following mandated activities presented below:

1. Training of individuals on the requirements for appropriate packaging and shipping of infectious substances, documentation of the training and subsequent certification of the trainee.
2. Classification and naming of the material to be shipped.
3. Selection of appropriate packaging to protect the transportation personnel in the event of being damaged.
4. Placing appropriate marking and labels on the outer package to alert carrier personnel and to identify contacts of the accidents occurs.
5. Documenting relevant aspects of each package and its contents.

F. USPS
The U.S. Postal Service (USPS) publishes its own regulations in the USPS Domestic Mail Manual. The USPS regulations for mailing hazardous materials generally adhere to DOT regulations.

Classification of Substances:

A. Classification
Shipping of all dangerous goods begins with classification of the substances. Classification is mandatory three-step process to define dangerous goods that are shipped by commercial carriers. Classification serves two purposes; it allows the shipper to select the proper IATA packing instructions, and it also provides the direction to use. If the substance is a category A infectious substance, it provides important information to complete documentation (a Shipper's Declaration) which must accompany shipments of Category A substances.

B. Steps of Classification

1. Step one: The material must be classified into one of the nine IATA-specified classes (Class1 through Class 9) of dangerous goods (IATA) **(Table B.1).** Infectious and toxic substances are

class 6 dangerous goods; dry ice is a Class 9 dangerous good. Class 6 and Class 9 substances usually are the only dangerous goods shipped by clinical laboratories.

2. Step two: Class 6 substances must be divided into either Division 6.1 (Toxic Substances) or Division 6.2 (Infectious Substances)
3. Step three: Division 6.2 infectious substances must be classified into one of nine IATA specified types of infectious substances **(Table B.2).**
   a. Category A Infectious Substances
   b. Category B Infectious Substances
   c. Patient Specimens
   d. Exempt Human or Animal Specimens
   e. Genetically Modified Organisms
   f. Exempt Substances
   g. Biological Products
   h. Infected Animals
   i. Medical Waste

   If the substance is determined to be a patient specimen or a genetically modified organism and is not a Category A or a Category B substance, but it meets the criteria of or has characteristics of a category A or Category B substance, the shipper must classify it as a category A or Category B substance. Otherwise, the substance must be classified as an Exempt Human or Animal specimen or a genetically modified organism **(Table B.2).**

***Table B.1**: IATA -Defined classes of dangerous goods:*

Class 1: Explosives
Class 2: Gases
Class 3: Flammable Liquids
Class 4: Flammable Solids
Class 5: Oxidizing Substances
Class 6 :Toxic and Infectious Substances
Class 7: Radioactive Material
Class 8: Corrosives
Class 9: Miscellaneous Dangerous Goods

Table B 2: *Type and Classification of IATA Division 6.2 Infectious Substances. Type of infectious substance classification IATA**

Category A Substance	Category A
Category B Substance	Biological Substance, Category B
Patient Specimen	
Meets Category A Criteria	Category A
Meets Category B Criteria	Biological Substance, Category B
Does not Meets Category A or B Criteria	Exempt Human or Animal Specimen
Exempt Human or Animal Specimen	Exempt Human or Animal Specimen
Genetically Modified Microorganism	
Meets Category A Criteria	Category A
Meets Category B Criteria	Biological Substance, Category B
Does not Meets Category A or B Criteria	Genetically Modified Microorganism
Exempt Substances	None
Biological Product	None
Infected Animals	None
Medical waste	None

***Abbreviation: IATA (International Air Transport association)**

C. Category A infectious Substances
A Category A substance is an “infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, or life-threatening or fatal disease to otherwise healthy humans or animals.

1. Deciding whether an infectious substance is a Category A substance is relatively easy because Category A substances are specifically listed by IATA and DOT **(Table B.3).**
2. Decisions to classify substances as Category A
   ATA requirements allow shippers to use their discretion and professional judgment when deciding if a substance meets Category A criteria. IATA Dangerous Goods Regulations (DGR) states the following:
   a. Regarding judgment-“Assignment to UN2814 or UN2900 must be based on known medical history and symptoms of the source human or animal, endemic local condition, or professional judgment concerning individual circumstances of the source human or animal”.
   b. Regarding assigning infectious agents which, in the shipper’s opinion, meet Category A criteria, but which are not specifically listed as a Category A agent-“Infectious substances which do not appear in the table but meet the same criteria must be assigned to Category A.”
   c. Regarding uncertainty of Category A criteria-“...if there is doubt as to whether or not a substance meets the criteria (of Category A), it must be included in Category A.
3. UN numbers of Category A pathogens
   Category A pathogens and substances likely to contain Category A pathogens must be assigned the UN number UN2814 (proper shipping name, infectious substances, affecting humans) or UN 2900 (Proper shipping name, Infectious Substance, Affecting Animals)

(Fig. C.1 and Fig. C.2).

4. Agents of Bioterrorism
   Some Category A pathogens have been designated as agents of bioterrorism and are known as select agents **(Appendix A.1).** U.S. federal regulations require shippers to have special permits to possess, use, transfer and receive these agents.

Table B.3 Indicative Examples of Infectious Substances Included in Category A

UN Number and Proper Shipping Name	Micro-Organism
UN 2814 Infectious substance Affecting Humans	Bacillus anthracis (cultures only) Brucella abortus (cultures only) 3 affecting humans Brucella melitensis (cultures only) Brucella suis (cultures only) 3.6 Burkholderia mallei–Pseudomonas mallei–Glanders (cultures only) Burkholderia pseudomallei–Pseudomonas pseudomallei (cultures only) Chlamydia psittaci–avian strains (cultures only) Clostridium botulinum (cultures only) Coccidioides immitis (cultures only) Coxiella burnetii (cultures only) Crimean-Congo haemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) Escherichia coli, verotoxigenic (cultures only) Ebola virus Flexal virus Francisella tularensis (cultures only) Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Mycobacterium tuberculosis (cultures only) Nipah virus

	Omsk haemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) Rickettsia prowazekii (cultures only) Rickettsia rickettsii (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only)
	Sabia virus Shigella dysenteriae type 1 (cultures only) Tick-borne encephalitis virus (cultures only) 3 Variola virus Venezuelan equine encephalitis virus (cultures only) 3.6 West Nile virus (cultures only) Yellow fever virus (cultures only) Yersinia pestis (cultures only)
UN 2900 Infectious substances affecting animals	African swine fever virus (cultures only) Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Goatpox virus (cultures only) Lumpy skin disease virus (cultures only) Mycoplasma mycoides–Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)

Fig. C.1 Algorithm for classifying infectious Substances

Is it known NOT to contain infectious substances?

Are the microorganisms non-pathogenic to humans and animals?

Have the pathogens present been neutralized or inactivated, so that they no longer pose a health risk?

Is it an environmental sample (including food and water) that is not considered to pose a significant risk of health risk?

Is it a biological product or a biological material (eg. Blood product, tissue, or organ)
subject to U.S. department of Health and Human Services or U.S. Department of Agricultural regulation?

Is it a dried bloodspot or fecal occult blood?

Is it laundry or medical equipment, or a used health care product that conforms to 29 CFR 1910.1030?

Is it forensic material that complies with U.S., state, local or Indian tribal government regulations?

Is it an agricultural product or food defined under the federal Food, Drug and Cosmetic Act?

Is it for transfusion or transplantation?

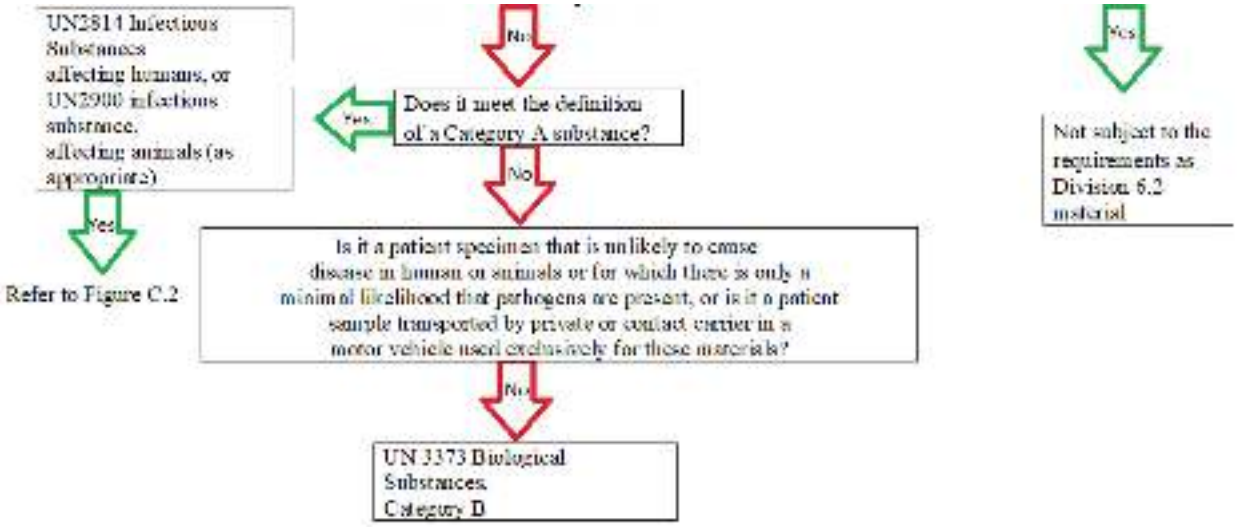
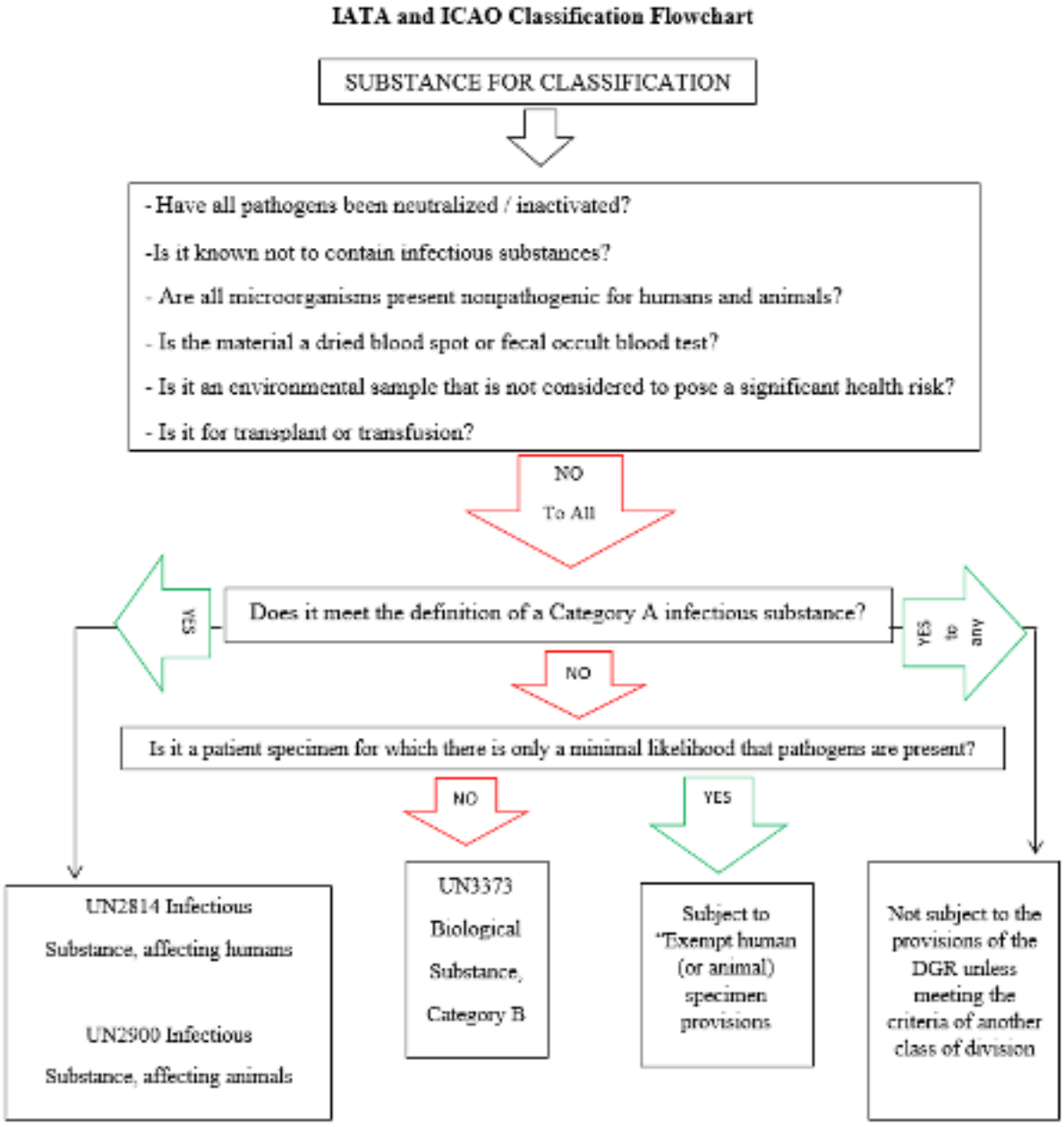


Fig. C.2 Algorithm for classifying infectious Substances



D. Category B infections Substances

A category B substance is defined by IATA as "an infectious substance which does not meet the criteria for inclusion in Category A **(Fig. C.1).** Category B substances are not in a form generally capable of causing disability, life-threatening illness, or fatal disease. Category B substances must be assigned UN number UN3373 (Proper shipping name, Biological Substance, category B).

E. Exempt Human (or Animal) Specimens
Exempt Human or Animal Specimens are those for which there is "minimal likelihood there are pathogens present." Examples of such specimens include urine or serum to be tested for glucose, cholesterol, hormone levels, prostate-specific antigens, and analytes used to evaluate heart and kidney function. Professional judgment and knowledge of patient medical history may be used to determine if the specimen is an infectious risk or contains pathogens. The IATA requires outer packages which contain Exempt Human or Animal specimens to be clearly labeled as "Exempt Human Specimen." The DOT does not require this label on the outer packages.

F. Exempt Substances
Many substances commonly encountered in the clinical laboratories are exempt from the strict dangerous goods shipping requirements which apply to Category A and B substances and to Exempt Human or Animal Specimens. The Following are examples of such exempt substances:
1. Substances which do not contain infectious substances or are likely to cause disease in human and animals.
2. Substances which contain non-pathogenic microorganisms.
3. Most environmental samples which do not pose a health risk to humans or animals.
4. Substances to be tested for therapeutic drug monitoring, insurance purposes, alcohol or drugs, pregnancy indicators, cancer and antibodies.
5. Dried blood spots and fecal occult blood screen specimens.
6. Blood and blood components collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissue organs intended for use in transplantation.
7. FDA-approved and FDA-licensed biological products.
8. ≤30 ml of 10% formalin per primary container when the formalin is used as a preservative of an infectious substance.

G. Patient Specimens
The IATA had defined a "patient's specimen" as material collected directly from humans or animals for diagnostic, treatment, prevention, investigational or research purposes. Patient specimens which have category A or Category B criteria should be classified, packed, and shipped as Category A or Category B substances. Patient specimens which have neither Category A nor Category B criteria should be packed and shipped as Exempt Human or Animal Specimens.

H. Genetically Modified Organisms
Genetically modified organisms usually meet either category A or Category B criteria. If this is the case, the organism must be classified as a Genetically Modified Microorganism (Class9; Miscellaneous Dangerous Goods) and packed and shipped as such.

I. Virtually all commercially available biological products as defined by the IATA are exempt from the packing and shipping regulations presented in this procedure. Examples of biological products include bacterial typing sera, vaccines, bacterial antigens, anti-microbial agents, reagents for identifying bacteria and reagents used in antimicrobial susceptibility testing.

J. Medical Waste
Medical wastes contain Category A or Category B infectious substances must be packed and shipped and assigned UN2814, UN 2900 or UN337. Medical waste which is reasonably believed to have a low probability of containing infectious substances must be packed and shipped as Medical waste (UN3291).

K. Infected Animals
A live internationally infected animal that is known to contain or reasonably expected to contain an infectious substance cannot be transported by air unless the substance cannot be transported by any other means.

Naming Category A and Category B Substances:

After classifying the substance, the shipper must identify a Category A or B substance by assigning the substance one of the over 3000 IATA specified and internationally recognized UN numbers and proper shipping names listed in the IATA requirements **(Table 1.1).**

Packing Instruction and Packing Substances:

A. PI
DOT and IATA regulations describe the minimum standards for the safe transport of various biological materials. After determining the exact nature and category of the substance to be shipped and the proper shipping name of the substance, the shipper must select the most appropriate PI and packing directions to use. Generally, the PI used by clinical laboratories are those that relate to shipping Category A infectious substances (PI 602),Category B infectious substances (PI 650)and dry ice (PI 904).There are no specifically numbered PI for specimens classified as Exempt Human or Animal Specimens; however, the IATA directions which must be followed.

B. Main Components of PI 602 and Pi 650:
The following are the main components of PI 602 and PI 650
1. A leaked poof primary container made of glass, metal or plastic and, if it contains a Category A infectious substance, sealed by a positive method (e.g., heat seal, metal crimp, or taped screw –cap lid). For Category A and Category B substances to be shipped in either passenger or Cargo aircraft, the maximum allowable volume per primary container is 50 ml (50 g) and 1 liter (4 Kg) for Category A and Category B substances, respectively.
2. Absorbent material sufficient to absorb all liquid contained within the primary container in case of breakage, placed between the primary and secondary containers. Absorbent material is not required if the material being shipped is a solid. Absorbent material should be used with liquids shipped in a frozen state.
3. A leak proof secondary container which contains the primary containers(s).
4. Either the primary or secondary container must be able to withstand an internal pressure of at least 95 pKa because shipments are likely to be placed into unpressurized cargo sections of aircraft which fly at high altitudes.
5. A list of the contents and quantities of the primary container(s) must be attached to the outside of the secondary container.
6. A rigid and durable outer package of adequate strength for its intended use and constructed of cardboard, wood or material of equivalent strength and which measures at least 4 by 4 in. on at least one surface. For shipping Category A infectious substances, these outer containers must meet strict UN manufacturing and testing specifications.

C. Packing directions for Exempt Human or Animal Specimens
Packing used with Exempt Human or Animal Specimens is less strict than the previously mentioned requirements in PI 650 and 602. However, such packaging must be composed of four important elements: (i) a leak proof primary container, (ii) a leak proof secondary container, (iii) for liquid substances, absorbent material of sufficient quantity to absorb the entire liquid, placed between the primary and secondary containers; and (iv) outer packaging of adequate strength for its intended capacity, mass and intended use".

Marking and Labeling Outer Packages:

Marking is the act of writing or typing information onto the outer surface of an outer package and labeling is the act of placing informational labels or stickers onto the surface pf an outer package. The two terms are frequently are used interchangeably. The shipper is responsible for the proper marking and labeling of the outer shipping package. The marking and labels on the outer container communicate essential information regarding the shipper and consignee of the package, the nature and weight of the content of the package, the potential hazard of the substance, how the substance is packed and information to be used in case of an emergency .Some of these markings and labels can be seen in the IATA DGR.

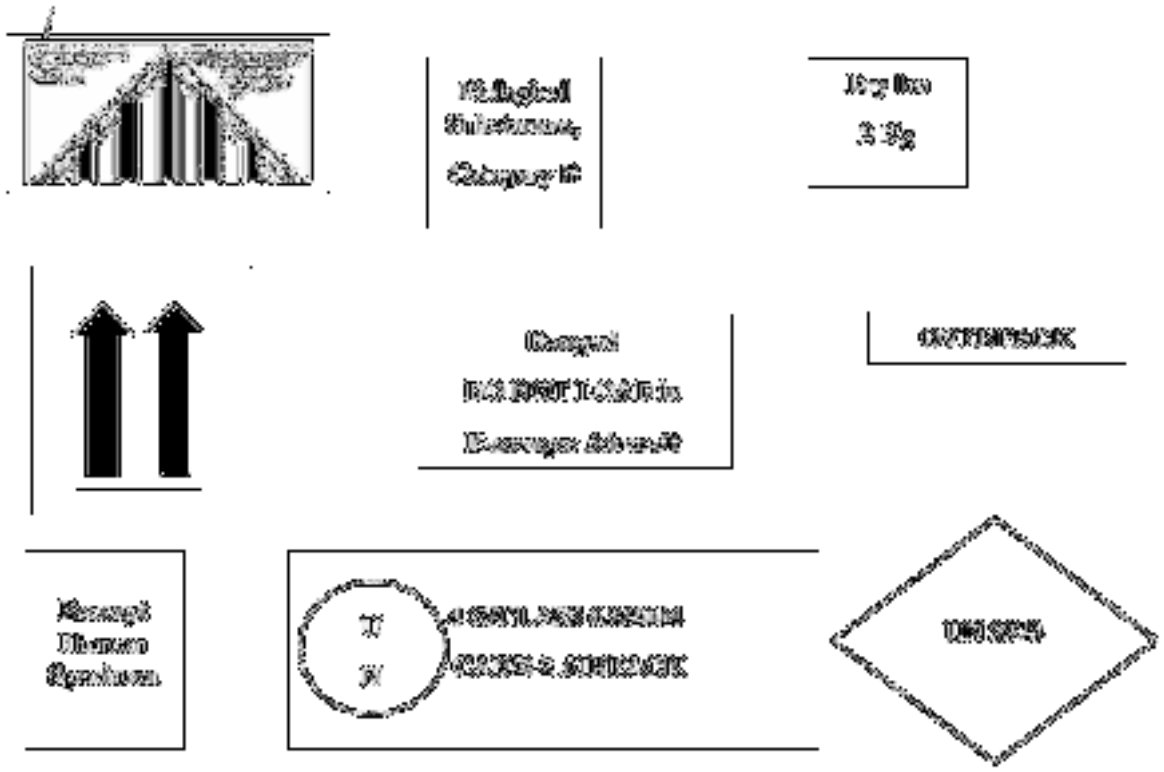
A. Specific markings and Labels
   1. Shipper and consignee –the shipper's and consignee's name and address.
   2. Responsible person-The name and telephone number of a "person responsible." If the substance being shipped is a Category B substance, this information may be provided either on the outer package or on the air waybill.

   NOTE: The person responsible in WCH-laboratory is the Laboratory Director or any designated person in his/her absence.

   3. Category A substances:
      a): The class 6 diamond-shaped "Infectious Substance
      b): A label that shows the proper shipping name, UN number and quantity of the substances
   4. Category B substances:
      a): The label "Biological Substance, Category B"
      b): The marking or label "UN 3373"
   5. Dry ice:
      a): Class 9 "Miscellaneous Dangerous Goods" label
      b): The weight of dry ice
   6. Package Orientation: Package Orientation label (arrows) must be placed on opposite sides of all packages which contain >50 ml of a liquid or frozen liquid infectious substances to indicate the correct orientation of the package.
   7. Cargo only: "Cargo Aircraft Only" label is applied if the substance must be transported only by cargo aircraft. This label is used if infectious substance amounts greater than 50 ml (5 g) but less than 4 liters (4 Kg) per outer package are shipped.
   8. Over pack- "Over pack" markings if over packs are used **(Fig. 8.1).**
   9. Exempt Patient Specimens**:** Patient specimens not classified as Category A or Category B must be labeled clearly as "Exempt Human Specimen" or "Exempt Animal Specimen" **(Fig. 9.1).** This requirement is specified only by the IATA and not by DOT.
   10. Outer package: All outer packaging used to ship Category A infectious substances and substances considered by the shipper to be an infectious risk to the health of carrier personnel must meet manufacturing and performance specifications established by the UN and must be marked as such by the manufacture. Packaging that meets the UN specification are marked by a "UN" inside of a circle and a series of letters and numbers which indicate the type of package, class of goods the package is designed to carry, manufacturing date, authorizing agency and manufacturer **(Fig. 10.1)**. The designation "class 6.2" in the marked code indicates that the container is approved for shipping infectious substances. These containers are commercially available and are preprinted with the appropriate UN marking. The strict UN specifications for outer packaging do not apply when shipping Category B substances. Outer boxes used to ship Category B substances need only to be rigid and strong enough for their intended purpose and be able to pass a 3.9-ft drop test.

B. Examples of labeled and marked outer packages

Figures **B.1, B.2 and B.3** show examples of completely labeled and marked outer shipping containers which contain an Exempt Human Specimens, a Category B infectious substance and Category A infectious substance, respectively. Packages in Fig. B.2 and B.3 also contain dry ice. For convenience and lower costs, one or more triple packages packed in full compliance with IATA regulations may be shipped within a single over pack which does not have to meet UN specifications. However, the over pack must be labeled “over pack,” and all inner package must be completely labeled according to applicable IATA regulations **(Fig. 8.1).**



Documentation:

A. A Shipper’s Declaration is a legal contract between the shipper and carrier, is required to document the shipment of Category A infectious substances, must be accurate and must be legible or the carrier may reject the package for transport. A shipper’s Declaration is required for dry ice (a dangerous good) if dry ice is used as a refrigerant for category A substance, but not for a Category B substance. Some carriers require the Shipper’s Declaration to be typed: some require multiple copies. The original Shipper’s Declaratio given to the carrier must have vertical red candy stripes along the left and right edges of the document. Shippers must retain copies of Shipper’s Declarations for 2years. All corrections must be neatly “lined out,” and all changes must be signed (not initialed) by the same person who signed the documents. A carrier may reject a shipment if each field on the Shipper’s Declaration is not completed exactly to the carrier’ satisfaction, and if the information and phrasing on the Shipper’s Declaration do not match exactly the corresponding information on the outer package. Commercial carriers and the Federal Aviation Administration often exercise their authority at airports to examine Shipper’s Declarations for compliance with applicable regulations and to open and inspect any package (whether or not the package is leaking) which contains or is suspected of containing an infectious substance. In addition, the agencies can and do examine documentation of perfectly packaged shipments, go

to the facilities from which the packages originated, and request documentation of adequate training of employees. A blank Shipper's Declaration form is attached at the end of this document. Essentially all of the IATA-specified technical information required to complete the seven substances of section "Nature and Quality of Dangerous Goods" of the document.

B. Emergency response telephone number
DOT, but not IATA regulations state that an "emergency response telephone number" must be provided on Shipper's Declarations which accompany shipments of Category A infectious substances. The number must be monitored at all times by a person (not an answering machine, message service, pager, etc.) who has knowledge of (i) the hazards of the material being shipped and (ii) emergency response and accident mitigation information in case a handler contacts the released contents of the package . Alternatively, the number can be that of a person who has immediate access to a person who has such knowledge and information. The number of an agency, organization or commercial company may be used instead of the person if the shipper can ensure that the agency, organization, or company can supply the required emergency information in a timely manner.

NOTE: The person responsible in WCH-laboratory is the Laboratory Director or any designated person in his/her absence.

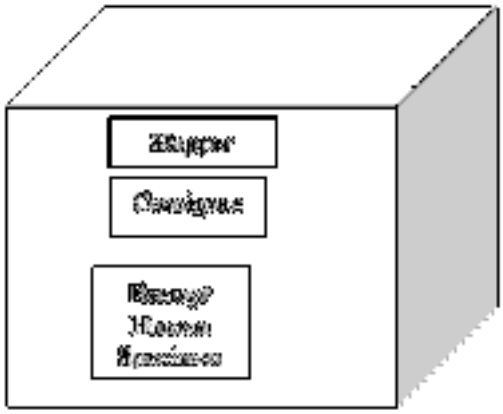


Fig.B.2

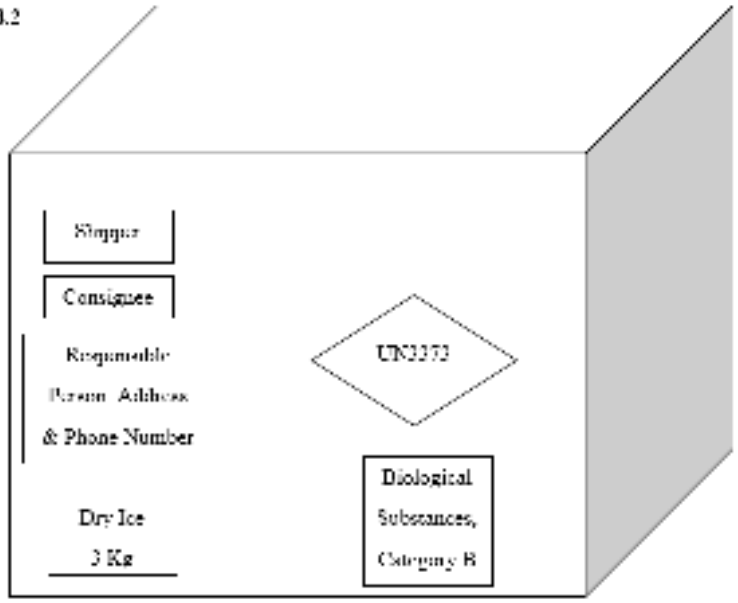
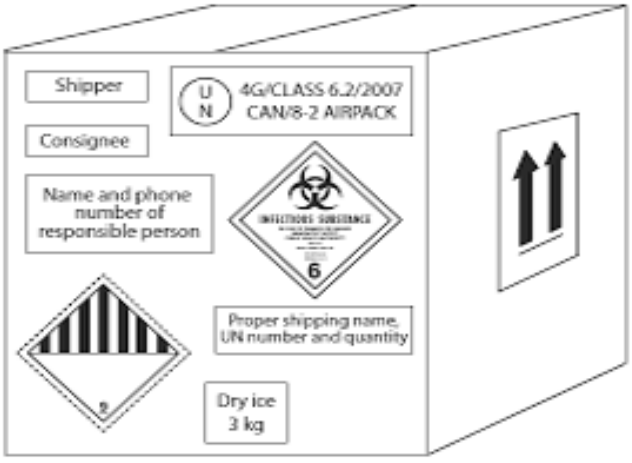

Shipper
Consignee
Responsible
Person Address
& Phone Number
UN2373
Biological
Substances,
Category B
Dry Ice
3 Kg

Fig.B.3


Shipper
UN
4G/CLASS 6.2/2007
CAN/8-2 AIRPACK
Consignee
Name and phone
number of
responsible person
6
Proper shipping name,
UN number and quantity
Dry ice
3 kg

Refrigerants:

Wet and dry ice are two common refrigerants used to ship diagnostic specimens and infectious substances. Packaging must be leak proof when wet ice is used. Dry ice is Class 9 dangerous goods, it must be packaged according to PI 904, and its use requires completion of a Shipper's Declaration if it is used to ship Category A substance. This secondary container must be secured so that it does not become loose as the dry ice sublimates. Outer packages must be labeled "Dry ice," and the net weight of the dry ice must be indicated on the outside of the outer package and be recorded on the Shipper's Declaration **(Appendix E.1).** The maximum permitted net weight of dry ice per outer package is 200 kg.

NOTE: Dry ice is an explosion-hazard and must never be placed into a tightly sealed container! Dry ice must be placed **outside** the secondary container and outer packaging must permit the release of CO2!

Carriers Responsibilities:

A. Provides the sender the necessary shipping documentation and instructions for their completion
B. Provides advice to the sender about correct packaging
C. Assist the sender in arranging the most direct routing and then confirms the routing
D. Maintains and archives the documentation for shipment and transport
E. Monitors required holding conditions of the shipment while in transit
F. Carries an appropriate
G. Notifies the sender of any anticipated delays in transit

Training and Certification:

The DOT and IATA provide surprisingly little direction and details for training shippers. Neither organization provides much helpful information regarding who should or can be a trainer how training should be performed, detailed contents of training, how testing is to be performed , the definition of a passing grade, and how to determine if a person is adequately trained.

A. Applicability
   Anyone involve in the shipping or transportation of dangerous goods must be trained and certified in the shipment of dangerous goods. 2005 WHO guidelines state that only persons who pack and ship Category A infectious substances must receive the formal training and certification. Persons who pack and ship Category B infectious substances and Exempt Human and Animal Specimens need to receive only general and practical training such as "clear instruction on the use of packaging "and "training and awareness" of the importance of packaging substances appropriately. Such persons should receive clear instructions, guidance and training appropriate for packing and shipping Category B infectious such substances and diagnostic specimens, addressing spills and protecting themselves.

B. Essential Components
   The essential components of a training program include the following:
   a. General awareness and familiarities with the many aspects of shipping dangerous goods
   b. Importance, nature and contents of IATA and DOT regulations
   c. Function-specific training
   d. Marking and labeling
   e. Documentation of shipments of dangerous goods
   f. Safety training
   g. Security training (if applicable to a trainee's job responsibilities)
   h. Testing

i. Issuance of a certificate after successful completion of the training

C. Training Materials
Acceptable training materials and methods include manual, training courses and workshops, all of which are commercially available from professional organizations and commercial suppliers of packaging materials for dangerous goods. Alternatively, a training program or workshop which includes hands-on training and demonstrations can be developed by any hospital, laboratory through the direction of a certified trainer. All training programs should be designed to provide initial and regular follow up training to each employee responsible for shipping and packaging infectious substances.

D. Documentation of training
The IATA and DOT require all aspects of training to be completed. The most important document used to prove appropriate and timely training is a certificate which is issued after training is complete. Employers should keep a record for each employee who is trained. The record should include employee name, location and date of training, name of the trainer, course content, documentation of testing, and a copy of a certificate of training. IATA and DOT certification is valid for 2 and 3 years, respectively.

E. Enforcement of Compliance
The DOT and the Federal Aviation Administration have authority to perform unannounced inspections of facilities that ship dangerous goods, and to inspect these facilities for compliance with the training regulations and to inspect training records at these facilities. Facilities which do not comply with prescribed regulations are subject to substantial fines.

Appendix A. 1.

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

1. Abrin[5]
2. *Bacillus cereus* Biovar *anthracis**
3. Botulinum neurotoxins*[,5]
4. Botulinum neurotoxin producing species of *Clostridium**
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)1,5
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol[5]
9. Eastern Equine Encephalitis virus[3,4]
10. Ebola virus*
11. *Francisella tularensis**
12. Lassa fever virus
13. Lujo virus
14. Marburg virus*
15. Monkeypox virus[3]
16. Reconstructed replication competent forms of virus containing any portion of the 1918 pandemic influenza the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin[5]
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)[4]
20. Saxitoxin[5]

South American Haemorrhagic Fever viruses:

21. Chapare
22. Guanarito
23. Junin
24. Machupo
25. Sabia
26. Staphylococcal enterotoxins (subtypes A,B,C,D,E)[5]
27. T-2 toxin[5]
28. Tetrodotoxin[5]

Tick-borne encephalitis complex (flavi) viruses:

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus 3,4

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus[3]
50. Classical swine fever virus[4]
51. Foot-and-mouth disease virus*[,4]
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*[3]
55. *Mycoplasma mycoides*[3]
56. Newcastle disease virus[2,3]
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus[4]

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

61. *Coniothyrium glycines* (formerly

29. Far Eastern subtype[4]
30. Siberian subtype[4]
31. Kyasanur Forest disease virus[4]
32. Omsk hemorrhagic fever virus[4]
33. Variola major virus (Smallpox virus)*
34. Variola minor virus (Alastrim)*
*35. Yersinia pestis**

Phoma glycinicola and Pyrenochaeta glycines)
62. Peronosclerospora philippinensis (Peronosclerospora sacchari)
63. Ralstonia solanacearum
64. Rathayibacter toxicus
65. Sclerophthora rayssiae
66. Synchytrium endobioticum
67. Xanthomonas oryzae

V. REFERENCES

https://www.who.int/csr/emc97_3.pdf

https://www.iata.org/en/publications/store/dgr-hazard-labels

VI. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	ABORh Retype	Policy #	BB131.001
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022~~09/2020~~

I. PURPOSE

To be in accordance with accreditation expectations to improve patient safety by reducing the risk of ABO incompatible transfusions, an ABORh Retype will be performed on a second sample of blood drawn at a different time when a patient has no previous blood bank record and there is either an order for blood products or the possibility of an order for blood products such as with a type and screen.

II. PRINCIPLE

As a prerequisite for this procedure, the Clinical Laboratory Scientist (CLS) must use the ABORh Retype Decision Tree to determine when ABORh Retype testing must be performed. The Decision Tree steps include:

1. Determine if there is a previous record
    1) For patients with no history, check for a second sample already in the laboratory that has been drawn at a different time and is within 3 days of the collection time of the Blood Bank specimen.
2. Test the original sample for ABORh
    1) An order for an ABORh Retype may be reflex generated at the time of result entry of the original ABORh by answering the history detail as “Yes” or “No” to “Previous History of ABORh Testing” or may be ordered on demand by the CLS before result entry.

III. POLICY

This SOP is for Clinical Laboratory Scientist trained in the blood bank section. The blood bank CLS will determine if an ABORh Retype is required and facilitate the obtaining the proper specimen.

1. The blood bank CLS will retrieve or print the label for the ABORh Retype and give the label to the Lab Technician to draw or retrieve an acceptable previously drawn sample.
2. The sample will be logged in the computer with the correct date, time and receiver.

IV. REAGENTS AND REQUIPMENT

A. Immucor® Anti-A, Anti-B, Anti-D, D control Anti-IgG (monoclonal)
B. Bovine Albumin at 8% (6.4mL saline and 3.6mL 22% albumin)
C. Normal Saline
D. Disposable Transfer Pipettes
E. Centrifuge
F. Cell Washer
G. 37° C Heat Block
H. Agglutination Magnifier/Viewer
I. Tubes, 10x75

V. STORAGE

Refrigerate 2-8° C the following products:

1. Immucor® Anti-A, Anti-B, Anti-D, D control Anti-IgG (monoclonal)

VI. SPECIMEN

A. No special preparation of the patient is required prior to specimen collection. Collect all blood samples using acceptable phlebotomy techniques. Blood should be drawn by aseptic technique, with or without anticoagulation.
B. The specimen should be tested as soon as possible after collection.
C. Preferred specimen: EDTA obtained from venipuncture, heelstick, or fingerstick tested at room temperature, stored up to 7 days at 2-8° C. The specimen is acceptable for ABORh Retype if stored at room temperature for eight hours.
D. Alternative specimen: Clotted whole blood (red top), however, a comment indicating the use of the clotted specimen should be added to the result comment.
E. Minimum volume: 0.5 mL for neonates and 1.0 mL for adults.

VII. QUALITY CONTROL

A. Control testing is to be done daily. Record results on QC Log. See Daily Reagent QC procedure.

VIII. PROCEDURE

A. Label test tubes for testing with the patient initial and: “A”, “B”, “O”, “D”, and “DC”.
B. Remove a small aliquot (2-3 drops) of patient blood and place in the labeled test tube.
C. Wash cord cells 4-6 times with large volumes of saline.
D. Resuspend the red cells in saline to a 3-5% suspension (refer to Preparing a Red Cell Suspension SOP).
E. Perform an ABO cells typing (forward only). No reverse Anti-A, Anti-B, because forward retype would confirm the initial ABORh.
F. In the SafeTrace Tx (Wyndgate) order a “Donation Test” depend on the patient’s ABO group.
G. Record the results in the SafeTrace Tx (Wyndgate) as they are read.

IX. DISCREPANCIES

A. Procedural Notes
    1. If the results of the confirmation testing do not agree with the original ABORh testing, do the following steps:
        1) Repeat the test on the original sample.
        2) Repeat the test on the ABORh Retype sample.
        3) If the ABORh group test still does not match, have the patient redrawn for a pink top ore re-band with a new red blood bank band number.
        4) Preserve original tubes of blood and the original red blood bank band and complete an Event Report and ERS
    2. For emergency release, group O blood is issued. An ABORh Retype must be drawn and completed before non-group O blood can be transfused. If the original patient sample is typed as Rh-positive but the ABORh Retype test has not been completed, group O Rh-positive may be crossmatched and issued.
    3. Same day surgery nurses will draw ABORh Retype tests at the time of admission either when the I.V. is started or as a second draw. If the patient is already in surgery, anesthesia or the surgical nurse will draw the test.
    4. For all other nursing areas, the Laboratory Technician will perform the ABO confirmation draw or be present in the room at the time of the line draw performed by nurse.
B. Discrepancies and/or issues that are not resolved shall be referred to the section head or a pathologist.

X. INTERPRETATION

a. Agglutination in the tube method is a positive (+) result and indicates the presence of the corresponding antigen. No agglutination in the tube method is a negative (0) result and indicates the absence of the corresponding antigen.

XI. LIMITATIONS

A. Contamination of blood specimens, reagent and/or supplementary materials.

B. Aged blood specimens, which may yield weaker reactions than those obtained with fresh red blood cells. Bloods older than the time limits stated under "SPECIMEN" may be tested with these Immucor® reagents, however, agglutination may be weaker with older red blood cells than with those from freshly drawn blood.
C. Tool light or too heavy a red blood cell suspension
D. Improper incubation time or temperature.
E. Calibration of the centrifuge is critical. Excessive centrifugation may lead to difficulty in resuspending the red blood cell button in the tube test. At the same time, inadequate centrifugation may yield unclear red blood cell button patterns and agglutinates that are too readily dispersed.
F. Improper examination for agglutination (usually too vigorous shaking). The resuspension of reactions in the tube test procedure must be carried out by gentle shaking. Shaking too vigorously may cause agglutinates to be dispersed.
G. Deviation from the recommended test procedure.
H. Very weak subgroups (of both A and B) may not be detected by these Immucor® reagents.

XII. REPORTING RESULTS

A. Record the ABORh Retype results in the SafeTrace Tx (Wyndgate).

XIII. ATTACHMENT

N/A

XIV. REFERENCES

A. AABB Technical Manual 19th Edition
B. Immucor® Blood Grouping Reagent package insert.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Rh Immune Globulin Prophylaxis	Policy #	BB2452
Responsible	Laboratory Director	Revised/Reviewed	12/15/2022~~01/2021~~

I. PURPOSE

Rh Immune Globulin is a concentrate of predominantly IgG anti-D derived from pools of human plasma. A full dose of anti-D (approximately 300 µg) is sufficient to counteract the immunizing effects of 15 mL of D-positive red cells. This corresponds to approximately 30 mL of fetal whole blood or the red cells in 30 units of D-positive platelet concentrates or three units of platelets by pheresis.

The protective effect of RhIG on D-negative individuals probably results from interference with antigen recognition in the induction phase of primary immunization.

SPECIMEN:

1. Collect a minimum 3 mL EDTA tube by venipuncture following laboratory protocol.

2. Postpartum testing for fetal-maternal hemorrhage is best performed on a specimen obtained as soon as possible after delivery of all products of conception.

II. POLICY

Widespread postpartum prophylactic use of Rh Immune Globulin (RhIG) has reduced pregnancy associated immunization to the D antigen to 1-2%. This risk is further decreased to 0.1% if RhIG is also given antepartum at 28 weeks gestation. The American College of Obstetricians and Gynecologists recommends antepartum RhIG prophylaxis.

If D-positive platelet components are administered to a D-negative individual, administration of RhIG should be considered. The D antigen is not detectable on platelets and post-transfusion survival of platelets from D-positive donors is normal in recipients with anti-D. However, even with proper preparation, platelet concentrates may contain up to 0.5 mL of red cells and platelets by pheresis may contain up to 5 mL; D-negative individuals may become alloimmunized by the residual D-positive red cells in a platelet component.

III. DEFINITIONS

N/A

IV. PROCEDURE

NOTE: To review a patient history:

1 -PATIENT during patient history review from within a worksheet

O -Orders *or* F7 -Pat view *or* F5 -Patient

D -Display O -Order O -Order

A. RhIG order during pregnancy - First trimester (□ 13 weeks gestation)

1. Review the patient history.

a. If an Rh has been performed during this stay, and patient is Rh(D) negative, or Rh(D) positive, DU variant, prepare RhIG for issue.

b. No Rh recorded during this stay:

1) Order an RH via 1-PATIENT, O-Orders, M-Modify
2) Perform an Rh test (see Rh Blood Typing).

3) If Rh(D) negative or Rh(D) positive, DU variant, prepare RhIG for issue.

2. The safest and most efficacious treatment is to give RhIG to any Rh(D)-negative woman after any procedure that could cause fetal-maternal hemorrhage, preferably within 72 hours. This includes:

- early termination due to ectopic pregnancy
- spontaneous or induced abortion
- chorionic villus sampling (CVS) or other invasive procedure
- threatened miscarriage where the pregnancy continues
- abdominal trauma

3. RhIG is not necessary if the patient is already known to be sensitized.

B. RhIG order during pregnancy - □ 13 weeks gestation, antepartum typically 28 weeks

1. Review the patient history.

a. Confirm that the patient is Rh(D) negative, or Rh(D) positive, DU variant

b. If there is no Rh history:

1) Order an RH via 1-PATIENT, O-Orders, M-Modify

2) Perform an Rh test (see Rh Blood Typing).

2. To determine whether active immunization has occurred, an antibody screen should be performed.

a. If the patient is an outpatient, the physician's office will order an antibody screen.

b. Perform the antibody screen (see Antibody Screen procedure for Capture-R)

c. Transfusion Service does not issue Rhogam for outpatients. The physician's office is responsible for stocking the Rhogam and giving the injection.

d. In the rare instance when the antibody screen is positive, notify the pathologist for consult with the patient's physician. The antibody must

be identified.

1) Order an ABpan via 1-PATIENT, O-Orders, M-Modify

2) Identify the antibody(ies) (see Antibody Panel procedure for Capture-R)

NOTE: During the third trimester there is the potential for excessive FMH (i.e., a fetal bleed >15 mL RBCs requiring treatment with more than a single 300 µg dose of RhIG). Accordingly, the need to quantitate the extent of the FMH, particularly in cases of trauma, should be considered.

3. If there has been antepartum hemorrhage or fetal death, the FMH Screen by rosette method should be performed, and if positive, a quantitative Kleihauer-Betke is needed to determine the appropriate amount of RhIG to be administered.

a. If the FMH Screen was not yet ordered during this stay:

1) Order FMH via 1-PATIENT, O-Orders, M-Modify

b. Perform the FMH Screen (see FMH Screen by Rosette procedure)

1) If the FMH Screen is negative, prepare a single RhIG dose for issue.

c. If the FMH Screen is positive:

1) Order K-B via 1-PATIENT, O-Orders, M-Modify

2) Perform the Kleihauer-Betke test (see Kleihauer-Betke procedure)

3) Prepare the calculated number of RhIG doses for issue.

4. All Rh(D) negative women in whom there is no evidence of active immunization to the D antigen should receive a RhIG dose at 26-28 weeks' gestation.

5. A dose should also be given to any Rh(D)-negative woman in whom there is no evidence of active immunization after any procedure that could cause fetal-maternal hemorrhage, preferably within 72 hours. This includes:

- spontaneous or induced abortion
- amniocentesis
- chorionic villus sampling (CVS), cordocentesis or other invasive procedure
- threatened miscarriage where the pregnancy continues
- abdominal trauma
- fetal manipulation (attempted external cephalic version)

6. Any woman receiving antepartum RhIG therapy should receive additional doses every 12 weeks until delivery; this particularly applies to women who received RhIG during the first trimester and to women who receive RhIG at 26-28 weeks' gestation but whose pregnancy extends beyond twelve weeks thereafter.

C. RhIG order postpartum

1. Review the patient history.

   Note: If the Softbank computer shows no previous labwork performed here, call the floor and request that the nurse check the patient's chart for prenatal labwork done elsewhere (i.e., Unilab). If the nurse can confirm that the patient's chart shows Rh and antibody screen testing done *during this pregnancy*, you do not need to repeat this testing. Add an order comment via 1.PATIENT, O-Orders, M-Modify, then F8-Edit Order Comment:

   "Prenatal blood typing and antibody screen performed at ….(Unilab, etc.) on 00/00/00(date)"

   a. Confirm that the patient is Rh(D) negative, or Rh(D) positive, DU variant
   If there is no Rh history:

      1) Order an RH via 1-PATIENT, O-Orders, M-Modify

      2) Perform an Rh test (see Rh Blood Typing).

   b. Confirm that there is no evidence of active immunity

      If there is no antibody screen on record during this pregnancy:

      1) Order an ABSCN (or tSCRN) via 1-PATIENT, O-Orders, M-Modify

      2) Perform the antibody screen (see Antibody Screen procedures for Capture-R or Tube method)

         - Tube method may be preferable since passive anti-D from RhIG administration is detectable within 24-48 hours and for as long as three months.

   c. In the rare instance when the antibody screen is positive, the antibody must be identified.

      1) Order an ABpan via 1-PATIENT, O-Orders, M-Modify

      2) Identify the antibody(ies) (see Antibody Panel procedure for Capture-R)

      3) In the rare instance when the antibody screen is positive for anti-D, notify the Pathologist for consult with the patient's physician.

         - An anti-D titer should be performed

            i. Order a Titer - Current (ztitr) via 1-PATIENT, O-Orders, M-Modify

            ii. Perform the titer (see Prenatal Titration of Antibodies procedure.)

   d. The fetus is presumed Rh(D) positive unless it has been shown to be Rh(D) negative.

      1) Cord blood testing for Rh is ordered for every Rh(D) negative mother

2) A RhIG order is initiated whenever the cord blood Rh is positive

3) If the fetus is Rh positive, Du variant, the FMH Screen may be invalid and a Kleihauer-Betke must be performed instead (see 2c. below).

2. To determine whether more than one dose of RhIG is necessary due to a large fetal-maternal hemorrhage, the FMH Screen by rosette method must be performed.

   a. If the FMH Screen was not yet ordered during this stay:

      1) Order FMH via 1-PATIENT, O-Orders, M-Modify

   b. Perform the FMH Screen (see FMH Screen by Rosette procedure)

      1) If the FMH Screen is negative, prepare a single RhIG dose for issue.

   c. If the FMH Screen is positive or the fetus is Rh positive, Du variant:

      1) Order K-B via 1-PATIENT, O-Orders, M-Modify

      2) Perform the Kleihauer-Betke test (see Kleihauer-Betke procedure)

      3) Prepare the calculated number of RhIG doses for issue.

3. If the mother is Rh positive, DU variant:

   a. An FMH screen can not be used to determine whether there has been a large fetal-maternal hemorrhage (because it will always be positive).

   b. Perform the Kleihauer-Betke test instead (see above).

D Platelet Transfusion - D-negative recipient of a D-positive platelet component

1. Review the patient history.

   a. If Rh(D) negative, notify Pathologist on the next business day of Rh(D) positive platelet transfusion including component (concentrate -vs- pheresis) and volume. If the next business day would be greater then 72 hours, i.e., a long holiday weekend, notify the Pathologist within 24 - 48 hours.

   b. No previous Rh on record:

      1) Order an ABORH via 1-PATIENT, O-Orders, M-Modify

         - If an ABO were needed for transfusion of RBCs or plasma, the results could be difficult to interpret if ABO incompatible platelets were transfused; determining ABO blood group prior to any transfusion is preferable.

      2) Perform an Rh test (see Rh Blood Typing).

      3) If Rh(D) negative, notify Pathologist as above.

2. The pathologist will consult with the patient's physician.

a. For immunologically normal D-negative females of childbearing potential, RhIG administration is recommended if administration of platelets from D- positive donors is unavoidable.

b. Patients who are thrombocytopenic because of cytotoxic therapy with concomitant immunosuppression may have a diminished risk of alloimmunization. The benefit of RhIG in this setting should be weighed against the risk of hematoma formation as a result of the injection.

3. If ordered, prepare RhIG for issue.

a. A full dose of RhIG, immunoprophylactic for up to 15 mL of D-positive red cells, would protect against the red cells in 30 units of D-positive platelet concentrates or three units of platelets by pheresis.

V. REFERENCES

i. Judd WJ. Methods in Immunohematology. 2nd ed. Miami, FL; Montgomery Scientific Publications, 1994
ii. Menitove JE, MD, chair, Standards for Blood Banks and Transfusion Services. 18th ed. Bethesda, MD; American Association of Blood Banks, 1997
iii. Vengelen-Tyler V, MT(ASCP)SBB, ed. Technical Manual. 12th ed. Bethesda, MD; American Association of Blood Banks, 1996

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Pending Worklog Wyndgate	Policy #	BB2738
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022~~12/2020~~

I. PURPOSE

All Result Entering, Selecting of Products and Product Modifications are done through the Pending Worklog. This window is used to display outstanding work order items and to provide access to the appropriate window for recording an ordered item's work. A query must be performed in order to display outstanding work order items. When work has been recorded for an order item it is removed from the Pending Worklog.

II. POLICY

xxx

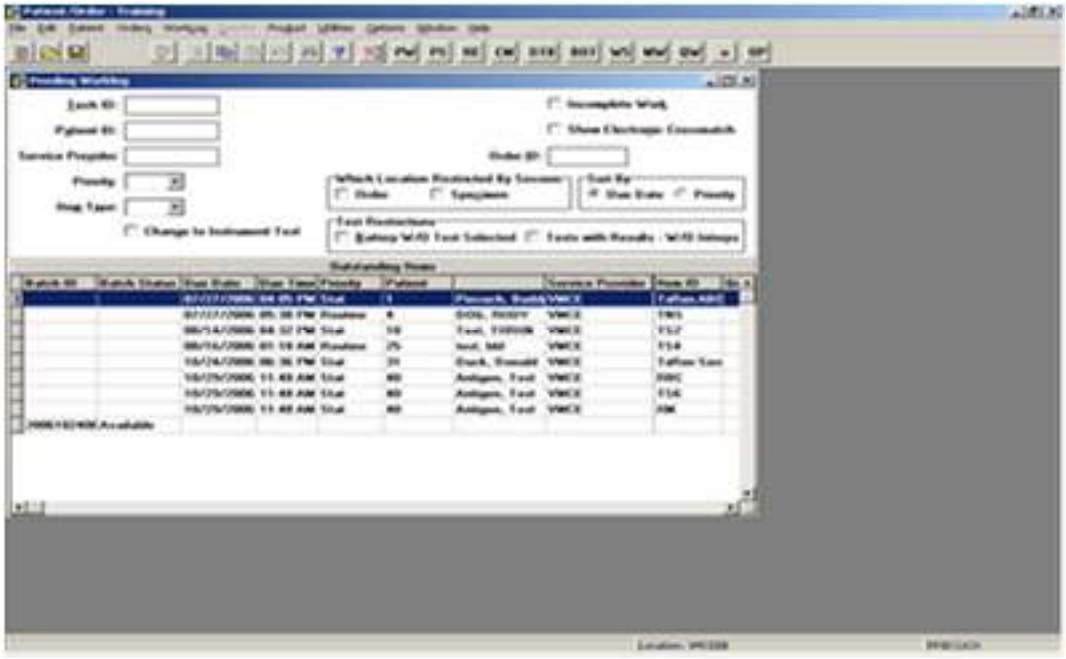
III. DEFINITIONS

N/A

IV. PROCEDURE

From the Patient/Order module:

1. Select the PW icon from the tool bar. The Pending Worklog will appear.
2. Press the red? Query icon (next to the PW icon) on the tool bar. This will display the pending work on the Outstanding Items grid. To view a specific order's items enter either the Patient ID or the Order ID, then Query (red?).



3. Select the appropriate Item. Click on the appropriate icon on the tool bar. Depending on the work item selected, RE (Result Entry) PS (Product Selection) or CM (Component Modify) may be selected. These options are only available from the Pending Worklog by selecting the corresponding work order item from the grid.

4. Once a user selects an item from the grid it is posted to that user's work queue and is not available for work by another tech unless deselected. (See deselecting from another user's Worklog procedure.)

V. REFERENCES

Safe Trace TX 3.0.0, Patient Order Training Manual, Wyndgate Technologies, January 2004.
Safe Trace TX, Quick Reference Cards, Wyndgate Technologies, Sept 2005.

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Entering Results: Crossmatch Results	Policy #	BB2742
Responsible	Laboratory Director	Revised/Reviewed	10/17/2022

I. PURPOSE

To provide procedure in resulting antibody screen and antibody identification.

II. POLICY

All Result Entering, Selecting of Products and Product Modifications are done through the *Pending Worklog*. This window is used to display outstanding work order items and to provide access to the appropriate window for recording an ordered item's work. A query must be performed in order to display outstanding work order items. When work has been recorded for an order item it is removed from the *Pending Worklog.*

III. DEFINITIONS

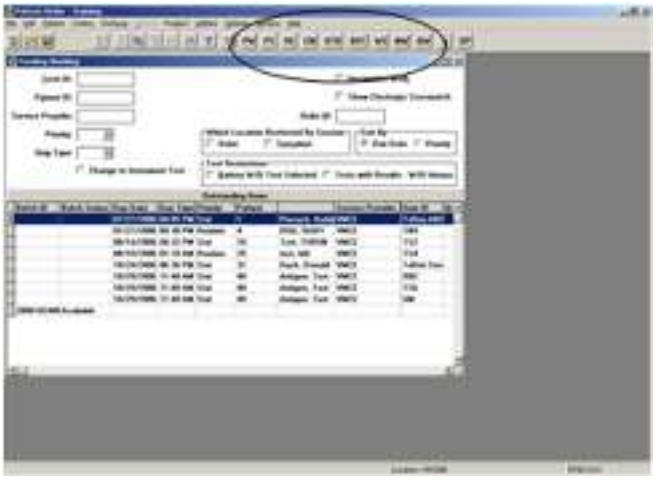
N/A

IV. PROCEDURE

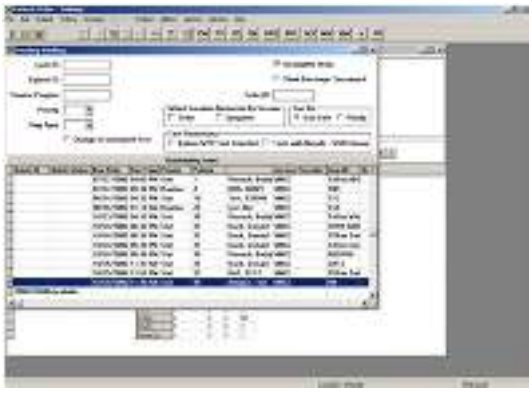
From the Patient/Order Module:

1. Select the **PW** icon from the tool bar. The *Pending Worklog* will appear.

2. Press the **red ?** *Query* icon (next to the **PW** icon) on the tool bar. This will display the pending work on the *Outstanding Items* grid. To view a specific order's items enter either the Patient ID or the Order ID, then *Query (***red ?).**



3. Select the Patient's **XM** item from the *Outstanding Item* grid.



4. Press the **RE** (*Result Entry*) icon from the tool bar. The *Result Entry* screen will appear.

5. The **specimen ID** must be verified before results can be entered. Bar Code specimen label or manually enter the Specimen ID and Press **Tab** or **Enter**

6. Select the crossmatch test in the **Test Results grid**.
    a) Select the binocular icon located on the tool bar.
    b) The **Select Test for Test Battery window** displays
7. On the **Select Test for Battery window,** select the appropriate crossmatch test for the patient. **Select the Ok button**.

8. The selected crossmatch test displays on the **Result Entry window**.
    a) Enter the subtest reactions and the interpretation.

9. Save and close the result window when finished recording the results.

V. REFERENCES

Safe Trace TX 3.0.0, Patient Order Training Manual, Wyndgate Technologies, January 2004.
Safe Trace TX, Quick Reference Cards, Wyndgate Technologies, Sept 2005.

VI. STAKEHOLDERS

N/A

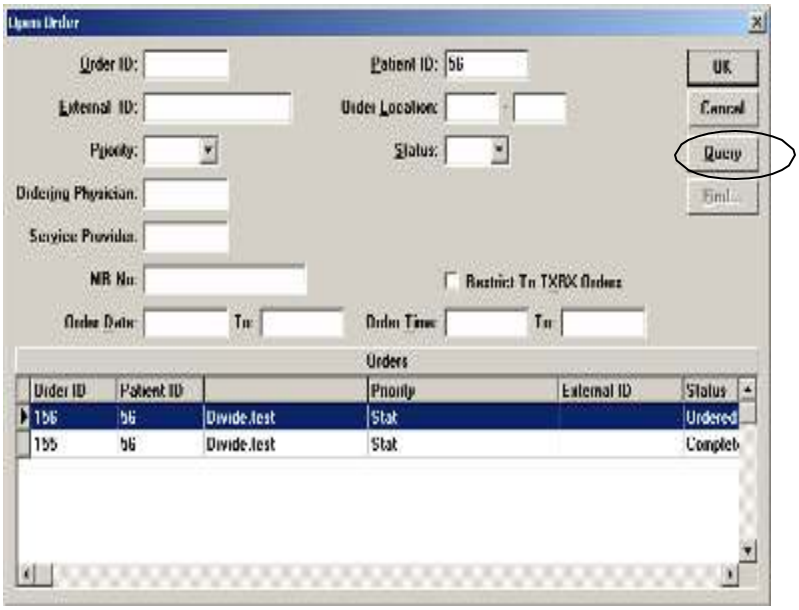
WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Transfusion Reaction: Recording Information	Policy #	BB2745
Responsible	Laboratory Director	Revised/Reviewed	10/17/2022

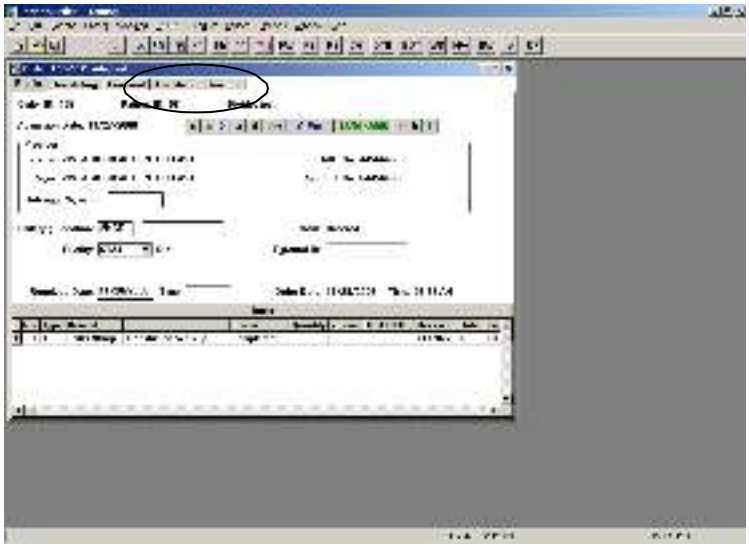
I. PROCEDURE

From the Patient/Order module:

1. Open the patient's transfusion reaction order. Select *FILE OPEN ORDER*. The *Open Order* window will be displayed.

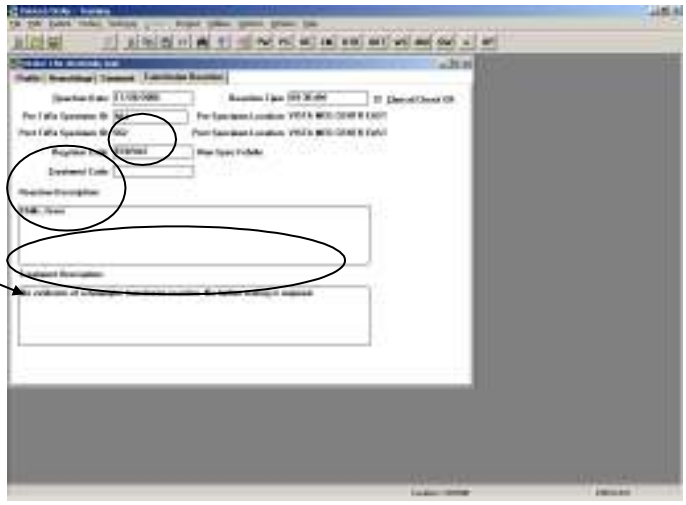


2. Enter the patient's order search criteria and select the *Query* button. Matching orders will be displayed on the *Orders* grid.
3. Select the correct order from the grid and select the OK button. The selected *Order Profile* window will be displayed.
4. Select the *Transfusion Reaction* Tab. The *Transfusion reaction* window will be displayed



5. Enter a **Reaction Code.** Use the *Binoculars* on the tool box or right click mouse to open drop down list of codes. Select appropriate code.
6. Free text the reaction description from the symptoms listed on the *Laboratory Services Report of Transfusion Reaction* form that is filled out by the nurse.
7. In the *Treatment Description* box, free text the pathologist's comments from the *Laboratory Services Report of Transfusion Reaction* form.

Free text Treatment Description must be recorded to update the TXRX order status to complete.



8. Select the Save icon on tool bar to save information.

II. REFERENCES

N/A

III. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Pathologist Review	Policy #	BB2755
Responsible	Laboratory Director	Revised/Reviewed	10/19/2021~~11/2020~~

I. PURPOSE
When to contact Pathologist.

II. POLICY
Guidelines are given for notifying pathologists of situations requiring review or consultation. The purpose is to provide consistent transfusion practice, monitor the appropriate use of blood products, and provide education as needed to both physicians and the CLS.

III. DEFINITIONS
N/A

IV. PROCEDURE
Call Stat:

1. The patient has a transfusion reaction performed and there is evidence of a transfusion reaction (new hemolysis, new icterus, or new positive direct coombs)
2. There is an unusual or extraordinary request for blood, components or services that requires immediate consultation from the pathologist.*
3. There is a request for the release of incompatible blood.
4. A patient has a severe reaction to platelets (larynospasm, bronchospams, pulmonary edema, shock)
5. There is an unresolved antibody identification and transfusion is imminent.
6. A massive transfusion (>10 units in 24 hours of packed red blood cells) with no concurrent FFP transfusions being given.

Call ASAP (day shift or as needed)

1. A patient has a transfusion reaction work-up performed. (fax to Dominican) Fax 462-7607
2. There is an unresolved antibody identification. (Send to the Red Cross) 1-408-577-2100
3. A prenatal patient is found to have a significant antibody.
4. There is a crossmatch for which few or no compatible units can be found
5. There is a request for the emergency release of uncrossmatched blood where the exigency may be questionable.
6. Inventory dictates that an Rh negative patient receives Rh positive units.

- *Unusual or extraordinary request may include requests for granulocytes, HLA matched platelets, cryoprecipitate on a non-hemophilia A, vonWillibrand or uremic patient,
- Utilization abuses may be held for the Medical Director Utilization situations may include one patient receiving more than 2 plateletpheresis in 24 hours, patient receives platelets on three consecutive days,

V. REFERENCES
N/A

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Identification and Banding of Transfusion Recipients	Policy #	BB2763
Responsible	Laboratory Director	Revised/Reviewed	10/17/2022

I. PURPOSE

To assure positive identification of all transfusion recipients.

II. POLICY

xx

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Patients

1. Compare the patient identification on the label requisition to the patient's hospital wristband. Any discrepancy must be resolved before proceeding. The phlebotomist is responsible for accuracy in identifying the patient. The phlebotomist must ask the patient to state their full name and date of birth which will be double checked against the requisition and written on the Blood Bank ID wristband. (BB ID was formerly known as the R number).
2. The bed label is NEVER used as a source of identification.
3. NEVER ask the patient to agree to a name.
4. If the patient is a non-English speaker, get assistance for identification, if none is available, you may use the LANGUAGE LINE at 1 (800) 523-1786, client ID 201120. This service will assist in any language to help in positive identification.
5. Write on the BB ID (R number) blood bank identification wristband, the patient's full correct name, date of birth, medical record number. These are required.
6. Include the phlebotomist initials, date of draw, and time of draw.
7. The specimen must be labeled at the bedside.
8. If the patient's identity is unknown, use emergency identification, for John Doe ER #1. This will then be cross-referenced with the patient's real identity when it becomes known.
9. Peel off the top of the BB ID white label and place on the EDTA 13 x 100 mm 6.0 ml draw tube with the BB ID towards the cap.
10. Place the wristband on the patient's wrist with the information visible.
11. Use an extender if the patient's arm is too wide for the band. Plastic waterproof covers are also available in Transfusion Services. These plastic covers require the band to be cut and fit into the cover, with all the information, including the BB ID visible.
12. Bring both the requisition and the extra BB ID armband labels to the transfusion service department, put the specimen in the centrifuge.
13. TRANSFUSION SERVICES WILL ACCEPT ONLY THOSE SPECIMENS THAT ARE COMPLETELY, ACCURATELY AND LEGIBLY LABELED. This is in compliance with AABB Standard 5.11.2.3.

NOTE: If the patient has a preexisting BB ID wristband, check with Transfusion Services first to determine if a new specimen is needed. If requesting to redraw the patient retaining the original BB ID, the above steps to positively identify the patients must still be taken. If a new specimen is requested to be drawn by the Transfusion Service CLS, the old BB ID armband must be removed.

B. Outpatient Preops
   1. The BB ID placed on the patient must remain until discharge from the hospital. This should be clearly indicated to the patient. Obtain language assistance is necessary.

C. Surgery
   1. Patients drawn in surgery for Crossmatch must also have a BB ID wristband. Laboratory personnel may fill out the BB ID and give it to the O.R. nurse who will verify the identity of the patient from whom the blood was drawn.

D. Armband Removal
   1. When medical conditions necessitate removal of BB ID wristband, a new band can be made with the same number. The band may be inserted into the plastic waterproof cover. Positive identity must not be compromised. The hospital personnel removing the armband must take responsibility for rebanding the patient. If a duplicate band is prepared, it must be noted as a duplicate with the date and initials of the preparer. If a preoperative patient has removed the armband at home yet has it in possession on arrival at the hospital, a duplicate may be prepared as above. No blood can be transfused to a patient without a BB ID wristband. If an armband has been removed without immediate replacement, any pre-transfusion testing must be performed again on a new specimen.

II. REFERENCES

N/A

III. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Fetal Bleed Screening Test by Rosette Method	Policy #	BB2800
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022

I. PURPOSE

FMH RapidScreen is intended for use in the detection of D-positive red blood cells in D negative mother

II. POLICY

A red cell suspension from the D-negative mother is first incubated with a reagent serum containing anti-D, and then washed to remove all unbound antibody. Instead of adding AHG (Anti-Human Globulin) to the washed cells, a weak suspension of D-positive red cells is added. After mixing, the tube is centrifuged and examined microscopically for mixed-field agglutination. Since any minor population of D-positive cells will have become coated with anti-D during the incubation phase, the D-positive indicator cells added after washing form clumps around the individual cells of the micro population. This results in larger and more readily detected agglutinates than could be expected to occur through the agglutination of a relatively small number of coated D-positive cells by AHG.

SPECIMEN:

1. EDTA tube collected from the mother by venipuncture following laboratory protocol.
2. It is best to wait about an hour after delivery to allow any fetal blood to mix thoroughly in the maternal circulation, but the sample should be collected as soon as possible thereafter.
3. If delay in testing should occur, specimen must be stored at 1-10 C until tested. Blood drawn into EDTA should not be stored for longer than two days, but the test must be carried out as soon as possible in any event, in order to permit the administration of Rh immunoglobulin within 72 hours of delivery.
4. Bacterial contamination of the specimen may cause false test results.
5. Do not use a grossly hemolyzed specimen for testing.

EQUIPMENT:

serological centrifuge	Blood Bank pipettes
10 X 75 mm test tubes	interval timer
Blood Bank saline, preferably PBS	
microscope slides and cover slips	microscope with low power(100-150 x)

REAGENTS:

The components of the kit may be interchanged between lots, providing they are in date. Store between 1-8 C. Do not freeze. Do not dilute. Do not use beyond expiration date. Effort should be made to minimize contamination and prevent evaporation during use of the product. Gently resuspend cell suspensions before using. Indicator cells must be well mixed before use.

1. Anti-D Reagent: A serum containing monoclonal IgM anti-D antibodies from the Human/murine heterohybridoma cell line GAMA401 grown in fluid culture diluted in a Proper diluent containing bovine albumin.

2. Indicator cells: An approximate 0.5% suspension of group O red cells obtained from a donor of the DcEe (R2r) phenotype.
3. Positive control: A 2-4% Suspension of red blood cells comprising approximately 99.4% of group O D-negative cells and about 0.6% group O D-positive cells obtained from a donor having heterozygous expression of the D-antigen.
4. Negative control: A 2-4% suspension of group O D-negative red blood cells.

QUALITY CONTROL:

1. The entire test procedure must be applied to both the positive and negative control cells in parallel with each batch of tests (or with each test if performed singly).\
2. The positive control confirms the reactivity of the indicator cells and provides an indication that the test is being carried out correctly. The positive control must demonstrate a positive reaction (five or more clumps per five low power fields).
3. The negative control test assures that the washing procedure has been sufficient to remove all unbound anti-D.
   a. A positive test result may be invalid unless the accompanying negative control test shows negative reaction (four or fewer agglutinations per five low power fields).
   b. The presence of agglutinates in the negative control would suggest that the indicator cells are being agglutinated by anti-D remaining in the control tube after washing. This may be a sign that the patient cells were inadequately washed. In this event, the test and controls should be repeated.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Test Method:

1. Make a 2-4% suspension of the maternal red blood cells to be tested in blood bank saline.
2. Place 1 drop of the prepared maternal suspension in a properly labeled test tube.
3. Place 1 drop each of the positive and negative controls in properly labeled test tubes.
4. Add one drop of the anti-D Antibody Reagent supplied with the kit to each tube.
5. Mix well and incubate for 5 minutes(+/- 1 minute) at room temperature (18-30 C)
6. Wash the cells four times using automated cell washer or by hand washing. Decant completely after last wash.
7. Add one drop of Indicator Cells and mix thoroughly by gently shaking the tube.
8. Centrifuge immediately for 15 seconds at 3400 rpm
9. Resuspend the cell button completely.
10. Examine microscopically for mixed-field agglutination using approximately 100x Magnification. This can be done either in the tube or on a slide.
11. If no clumps are seen in the tube and the quality control is found acceptable (see Quality Control above), record and report as negative.
12. If clumps of agglutinated red cells are seen in the patient tube, transfer the contents to a microscope slide and cover with a cover slip.
    a. Examine five low-power fields and count the number of mixed-field agglutinates rosettes) seen.
    b. If less than five clumps are observed in five fields, the test is recorded and reported as negative.
    c. If one or more clumps are observed in five low-power fields (five or more clumps per five low-power fields), the test is recorded and reported as positive.

B. Interpretation:

1. Negative test:
   a. Indicates it is unlikely a fetal-maternal hemorrhage of greater than 30mL whole blood has occurred.
   b. One standard dose of Rh Immune Globulin (RhIG) should be sufficient for immunoprophylaxis.

2. Positive test:
   a. Indicates that a quantitative test is required to determine whether the fetal-maternal bleed was sufficient to warrant multiple doses of Rh Immune Globulin to the mother. The number of clumps observed may be influenced by several variables in the performance of the test procedure, and should not therefore be used as a means of quantitating the amount of feto-maternal hemorrhage.
   b. A positive FMH screen must be quantitated using a Kleihauer-Betke stain.

V. LIMITATIONS

1. Contaminated materials, improper incubation time, temperature centrifugation, examination for agglutination and deviation from the recommended test procedure may cause false test results.
2. Correct interpretation of the test results presupposes that the test was performed on the blood of a known D-negative mother of a recently delivered D-positive child.
   a. If the infant's red blood cells possess a weak D (Du) antigen, the test may not detect an FMH exceeding 30 mL of whole blood.
   b. If the mother is D-positive, including Du positive, strong agglutination provides no information about the volume of FMH.
   c. If the infant is D-negative, a negative test result can be expected, irrespective of the volume of FMH.
3. In cases of ABO incompatibility between mother and child, the mother's natural ABO antibodies may destroy any fetal cells in the maternal blood specimen before testing is performed. This is true for any method of detecting fetal cells in the maternal blood.
4. Failure to carry out the washing stages of the test procedure properly may cause a false-positive test result, due to agglutination of the indicator cells by free anti-D remaining in the test system.
5. A false-positive result may occur if the maternal red blood cells have a positive direct antiglobulin test due to an autoantibody capable of reacting with the indicator cells.
6. A positive test result by itself does not provide evidence that an increased dose of Rh Immune Globulin is required. A positive test merely indicates that a larger than normal FMH may have occurred. A quantitative procedure is required to determine the FMH volume
7. The reactivity of reagent red blood cells may diminish over the dating period.
8. Do not use grossly hemolyzed specimen for testing.

I. REFERENCES

1. Product insert, Gamma Biologicals, Inc., *Gamma FMH RapidScreen test 03/2012*

II. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Blood Bank Refrigerator Alarms and Maintenance	Policy #	BB2818
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022

I. PURPOSE

Refrigerators for storing blood components must have an audible alarm to warn of abnormal temperatures. The alarms must be monitored to ensure that the blood components are maintained at safe temperatures. Alarms are audible/visible in the laboratory, as well as in the emergency room registration area. This remote alarm in ER registration is intended as a secondary notification, so that if the laboratory alarm fails or is not heard, laboratory personnel will be alerted to the abnormal temperature immediately.

APPARATUS:

A. Alarm Sensor
   1. Refrigerator
      - Located in a container of 10% glycerol in water, mounted on the upper inside wall of the Transfusion Service refrigerator. It is a large metal probe connected with flex-conduit.

B. Remote Alarm
   - Located in ER registration area. It is an audible/visible alarm which is activated simultaneously with audible/visible alarm on the refrigerator in the lab.

II. POLICY

The quality of blood is ensured by keeping the units stored at the proper temperature in the Blood Bank's refrigerator.

A. The refrigerator uses a paper chart to continuously monitor the temperature, as well as twice daily visual recordings.
B. The thermometer and alarm are checked quarterly as per AABB.
C. Out of range temperature alarms will be documented.
D. In the event of an emergency, there is a procedure for storage of the blood units.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. EMERGENCY PROCEDURES:
   1. Jordan Refrigerator is set to alarm at more than 5.9 degrees C. or less than 1.6 degrees C. (may be set at 5.5-5.9 C or 1.1 to 2.0 C.) If the alarm sounds:
      a. Press the red mute button.
      b. Document the incident in the alarm/QC log.
      c. Record the date, reason for alarm (if any available), temperature of alarm activation and notification of remote alarm by Emergency Department Registration (call ER registration if they have not called us)
      d. Any corrective action taken.
      e. Annotate on the temperature recording chart with the reason and initial.
      f. Check for open door or unplugged cord.

g. If unable to correct, notify Engineering Department.

2. After unsuccessful troubleshooting, if temperature does not correct and the units are in danger of warming:

   a. Relocated the units to another refrigerator. Include a portable thermometer to be placed next to the units inside the refrigerator.
   b. Call Biomed and/or Engineering for the TempTrace (room temp chart recorder) to place in the refrigerator with the blood as a back-up monitor (if available).
   c. ***Take temperature readings and record every 4 hours.***
   d. In a power and generator failure, blood may be placed in insulated containers with wet ice. The blood will be maintained between 1-6 degrees C as long as unmelted ice remains in contact with blood bag***.*** Add ice in a volume at least equal to the total volume of the units being stored.
   e. If no wet ice is available, chemical ice packs and even ice chips stored in the freezer may be used but may be too cold and can cause hemolysis if in direct contact with the unit. If chemical cold packs are used, several layers of paper towels must be placed between chemical ice packs and units.
   f. The Medical Director will decide final disposition of blood, and if ARC should be contacted.

   HEMOTEMP II PLACEMENT FOR INSULATED CONTAINERS

   i. Apply Hemotemp II stickers on representative units in each container.
   ii. Wipe blood bag free of moisture and oil.
   iii. Pull strip from box. Tear off individual HEMOTEMP II tag at perforation.
   iv. The irreversible portion of the indicator (blue “flower”) must be activated by heating. Warm the tag by dipping it into the water (37-40 degrees C) or placing it face down on the incubator surface for **60-80 seconds**. Check that the “flower” is blue.
   v. After the “flower” has turned blue, immediately press tag with backing removed firmly onto the center or near the bottom of blood bag.
   vi. Check the color of the “flower”. If it appears non-blue, the indicator has not been properly activated or the blood is warmer than 4 degrees C.

   HEMOTEMP II READING

   i. The Hemotemp II indicator must not be used as the sole indicator of acceptability of blood. Temperature of the container must be taken and recorded every 4 hours if not in a continuously monitored refrigerator.
   ii. In reading the Hemotemp II sticker, the reversible number must be visible and the irreversible flower must be blue for the units to be acceptable for transfusion.

3. The hospital electrical generator function and performance is checked at least weekly by the Engineering department. The unlikely even of a prolonged instance of power and generator outage could necessitate transport of blood and components to another facility. This must be accomplished before unacceptable storage temperatures are reached. Such decisions would be made in conjunction with the ARC and under the direction of the hospital administration and/or the Laboratory or Medical Director, whomever is available.

B. TEMPERATURE RECORDING:
   1. Temperature must be maintained between 1-6 degrees C.
   2. Alarm must occur before blood reaches either 1 or 6 degrees.
   3. Twice per day, AM and PM:

a. Record the digital temperature from the display on the outside of the refrigerator for both upper and lower solutions. To switch from one to the other, press the "step" button. Reading 1 is the upper solution, 2 is the lower solution (3- is the air temperature and not recorded.)

4. Once daily (in AM) observe and record the temperatures of the two portable thermometers placed on the lower and upper shelves. These thermometers are in containers filled with fluid to a volume no greater than the volume of the smallest component stored.
5. Check that the continuous temperature recording chart is indicating the correct day of week and time, and is agreeing with the upper solution digital reading within +/- 1 degree C. Adjust, as necessary.
    a. Annotate any temperature variations that fall outside of acceptable ranges as they occur.
    b. On Tuesdays, change temperature recording chart.
    c. New and used recording charts are kept in the original packages, in the drawer under the platelet hut.
    d. Press # 3 located above the chart, for one second to move the pen to an area of the paper chart that will allow for removal of the paper chart
    d. Prior to insertion of a new chart: date and initial, check that the hospital address is stamped on the reverse (the entire box may be stamped with the hospital's name upon receipt.)
    e. Recheck the temperature chart after several hours of changing to ensure it is functioning correctly.
6. Check on the Daily Transfusion Check off list under "chart ok" that the above #5 was completed.

C. THERMOMETER CALIBRATION
1. See Policy #1854, Guidelines for Thermometer Verification.

D. QUARTERLY QUALITY ASSURANCE TESTING
1. Low Temperature Alarm Activation

Materials needed:

Calibrated thermometer capable of reading -4 to 30 degrees C.
Pan large enough to hold a container of the thermometer and the thermocouple
Container for thermometer and thermocouple
Water, crushed ice
Table salt

a. Immerse a calibrated thermometer and the thermocouple in a container
b. Place this container in a pan of ice and water at a temperature of -4 degrees C. Several spoonful's of table salt may be used to obtain this temperature.
c. Close the refrigerator door to avoid changing the temperature of the storage compartment.
    i. Keep the container in the pan of cold slush and gently agitate it periodically until the alarm sounds.
    ii. Record this temperature as the low-activation temperature.
d. This temperature must be between 1.1 and 2.0 degrees C.

2. High Temperature Alarm Activation
    a. Immerse a calibrated thermometer and the thermocouple in a container.
    b. Place container in a pan of cool water (12-15 degrees C)

c. Close the refrigerator door. Allow fluid in container to warm slowly with occasional agitation.
d. Record the temperature at which the alarm sounds as the high-activation temperature.
e. Record the date of testing, the refrigerator identification, the thermometer identification and person performing the test.
f. If the temperatures of activation are too high or too low, take appropriate corrective action. Record these actions and repeat the alarm check to document that the corrections were effective.

ALARMS

1. If sensor temperature falls outside acceptable range, the alarm on the refrigerator will sound, and red light will flash. At the same time, alarm will sound in ER registration, and alarm light will flash.
2. Personnel working in ER registration must immediately call the lab (X1237) and notify them that alarm is sounding. If unable to reach anyone in the lab, such as on night shift, they may need to have the operator page the lab.
3. Laboratory personnel will then take necessary steps to correct the problem, troubleshooting shall include checking for the following: unclosed door, insufficient refrigerant, compressor failure, dirty or blocked heat exchanger or loss of electrical power.
4. The alarm will continue to sound until temperatures have been restored to proper range.
5. Call Engineering or Biomedical if unable to resolve temperature issues.
6. Inform Laboratory Director

V. REFERENCES

1. Price, Thomas MD chair, Standards for Blood Banks and Transfusion Services. 26th. ed. Bethesda, MD; American Association of Blood Banks, 2009
2. Roback, John MD AABB Technical Manual, 17th Edition, Bethesda, MD. American Association of Blood Banks, 2011
3. Sazuma, K., MD ed, Accrediation Requirements Manual of the AABB, 6th. ed., Bethesda, MD American Association of Blood Banks, 1995.

VI. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Frozen Plasma Transfusion	Policy #	BB2819
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022~~01/2021~~

I. PURPOSE

Plasma separated and frozen within 24 hours of collection contains stable plasma proteins and clotting factors and can be stored at -18 degrees C or colder for up to 12 months from date of collection. Thawed plasma (FP24) is used to treat bleeding associated with coagulopathy deficiencies.

II. POLICY

A. FP 24 is kept frozen at temperatures less than -18 C.
B. Patient must have BBID arm band. If no ABO is ordered, call floor and ask for them to order the ABO.
C. Thaw group compatible plasma, disregarding Rh type, with the earliest expiration date.
D. After thawing, FP 24 is stored at 1-6 degrees C. Unit expires 24 hours after thawing.
E. Do not refreeze after thawing.
F. If type specific plasma is unavailable, use following chart as a guide for selecting compatible plasma:

Patient Group	Compatible Plasma
O	O,A,B,AB
A	A, AB
B	B, AB
AB	AB
UNKNOWN	AB

G. FP 24 must be placed in a plastic overwrap before insertion into the water to prevent contamination of the container entry ports.
H. The thawed plasma must be removed from the waterbath as soon as it is thawed, it must not remain in the waterbath after the thawing is completed.
I. Waterbath temperature should be 33-37°C.

III. DEFINITIONS

N/A

IV. REAGENTS AND EQUIPMENTS

A. HelmerQuick Thaw DH 4

1. Maintenance Schedule:
    1. DAILY:
        a. Check the water level, water should be at the top mark at the back of the chamber. Add more (DI) water if needed.
    2. WEEKLY:
        a. Clean the outside and top inside of the chamber,
        b. Clean the plastic grey lid.
        c. Drain, clean and refill the chamber if needed.
    3. QUARTERLY:
        a. Clean the fan. See Helmer Manual for details
        b. Lubricate the moving parts, Biomed may assist.

c. Check the temperature calibration, adjust if needed
d. Test the high temperature alarm.
e. Record on TS Annual Maintenance Schedule.

4. ANNUAL:
   a. Check the bearings on each basket (Biomed)

2. SAFETY:
   1. Keep fingers and clothing away from baskets
   2. Temperature Alarm will prevent the process to start.
   3. A lift out malfunction alarm on one basket will not prevent starting other basket.
   4. DO NOT manually lift out basket.
   5. PRESS LIFT OUT button each time to life the basket.
   6. Turn off and disconnect before draining.

V. PROCEDURE

A. Thawing Procedure.

1. Determine if a plasma has been requested in Wyndgate or downtime form.
2. Call ordering area if no BBID arm banded specimen is available and request an ABO test. Have phlebotomist draw and band the patient per WCH TS department protocol.
3. Perform ABO and choose one type of specific unit from freezer with the earliest outdate. Disregard Rh type.
4. Remove the waterbath cover if needed.
5. Press LIFT OUT button to raise and open baskets.
6. Thaw FP 24 in overwrap. Overwrap bag must be used as it secures plasma bag to the basket and protects the plasma from contamination as well as the bath in case of breakage.
7. Place overwrapped plasma bag in basket, hooking top overwrap slot around top basket tab.
8. Lower the basket by pressing the LIFT OUT button.
9. Make sure the agitation switch is turned on (located on back right of instrument.)
10. Press CYCLE START to begin agitation.
11. **Cycle time should be set for the minimum time that the bag needs to thaw.** (It should be left at a preset of 10, electrical shut off will negate this preset.) Add more time if need.
12. Do not manually lift basket out of the Helmer chamber, as this damages the lift system. Press LIFT OUT button every time.
13. Press the LIFT OUT button only if the basket is attached to the lift-out system. Basket weight is required for proper positioning during operation.
14. Agitation reduces thaw time. Enable the agitation using switch located at back of thawer. The top switch controls the right basket, and the bottom switch controls the bottom basket.
15. Lift out system closes basket and lowers it into chamber. Basket starts agitating (if enabled) Remaining cycle time (in minutes displays on indicator.
16. Select the preprogrammed CYCLE TIME by pressing the button. The time will scroll from 3 minutes up to HO for hold. Do not leave on HO unless a timer is set.
17. Thaw time for 250mL bag should be approximately 10-16 minutes.

B. Computer/Label Procedure

1. After editing the specimen with the current correct BBID, and typing the ABO in Wyndgate, choose the PW and red? to choose the plasma line.
2. Press the PS (product selection)
3. Barcode the thawed unit information from the unit or manually enter.
4. Check the box labeled “print product ID tag” and print the PTAG.
5. Recheck the PTAG for accuracy; recheck the FP 24 bag for leaks, clots, hemolysis, cloudiness, bubbles, or other indications of deterioration.
6. Place the PTAG sticker on the FP 24 bag, and cover the original expiration date on the front of the unit.
7. Cross out the original expiration date on the front of the unit.
8. Using a white sticker, write the thaw date and time and correct expiration date and time (24 hours after thaw).
9. Place unit on top shelf of Jordan Blood Product Refrigerator (1-6 degrees C)
10. Issue within 24 hours or discard unit.

C. Broken Units

1. Remove unit from bath, discard overwrap and decontaminate any spills.
2. Write unit number and product code on the “Discarded units for Red Cross Credit” clipboard.
3. Log the occurrence in the Error/Variance log book.
4. Discard the unit in Wyndgate Inventory with the reason BRKN – broken.
5. Thaw a new unit if needed.

D. Inventory Management

1. Thaw one unit at a time unless need is dire.

VI. REFERENCES

A. Standards for Blood Banks and Transfusion Services, 27th Edition 2011 Technical Manual 17th Edition, 2011.

VII. STAKEHOLDERS

N/A

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	Antibody Screen-Gel Ortho Clinical Diagnostic	Policy #	BB2828
Responsible	Laboratory Director	Revised/Reviewed	10/19/2022~~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

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.

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.

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.

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

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Gel Panel AB Identification	Policy #	BB2829
Responsible	Laboratory	Revised/Reviewed	10/19/2022~~12/2020~~

I. PURPOSE

To identify unexpected antibodies detected in the antibody screen. The AABB recommends a panel be used after a positive screen to detect as many clinically significant antibodies as possible, as few insignificant antibodies as possible and to do this is a timely manner. An antibody is considered clinically significant if its specificity has been associated with hemolytic disease of the fetus and newborn, hemolytic transfusion reactions or with notably decreased survival of transfused red cells. Antibodies reactive at either 37 degrees C or in the AHG phase are more likely to be clinically significant than are cold reactive antibodies. Plasma is usually tested against a panel of eight or more group O cells of known antigenic composition. Positive reactions are compared to reaction patterns of the antigen present on the red cells. The reactions are evaluated to identify the antibodies present. An auto control is run in parallel with the panel.

II. POLICY

When an unexpected antibody has been detected in a sample, as seen from a positive antibody screen, further work up is needed to detect possible significant antibodies in the patient's plasma. Antibody identification is accomplished by testing the plasma against a panel of red cells having different antigen characteristics, observing the presence or absence of hemolysis or agglutination and comparing the pattern of reactivity with the antigen profile of the cells. 0.8% Resolve Panel A consists of human red blood cells from 11 group O individual donors and an antigram antigen profile. 0.8% Resolve Panel B reagent red blood cells is available should additional cells be required for the resolution of complex mixtures of antibodies.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Specimen

1. EDTA whole blood correctly labeled, less than 72 hours old. Specimens are stored in the blood bank red cell refrigerator in the specific day of draw's bin on the second to bottom shelf. These daily bins are rotated and discarded on the 14th day. Serum may be used if complement-dependent antibody is suspected.
2. For pretransfusion testing all tubes must be labeled according to laboratory protocol which includes the patient's name, medical record number(if available), date of birth and the transfusion service identification number (BB ID).The specimen must also have the phlebotomist's initials and date and time of draw. See "Identification and Banding of Patients" and "Transfusion Service Specimen Labeling" procedures. In downtime situations, a medical record may not be available, in that case, the full name, date of birth, BB ID and date/time and initials of phlebotomist will suffice.
3. Transfusion services shall only accept those specimens that are completely, accurately and legibly labeled.
4. The completed label shall be affixed to the tube before the phlebotomist leaves the patient's room, it must have the phlebotomist's initials and date and time of draw. If the phlebotomist is observing the draw and labeling the tube, both the person obtaining the blood (student, line) and the laboratory phlebotomist's initials (identifying and labeling the sample) should be on the tube.

B. Reagents

1. 0.8% Resolve Panel A or B. Use directly from a well mixed vial for each microtube. The reactivity may decrease during the dating period. This rate is dependent upon the individual donor's characteristics. Do not use if marked hemolysis or evidence of contamination is observed.
2. Anti-Human Globulin Anti-IgG (Rabbit) MTS Anti-IgG cards. Do not use if gel is absent or 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. Do not use if gel card shows signs of drying, discoloration, bubbling, or crystals. View each side of the card prior to use. Do not use if cards were not shipped and stored in an upright position. Do not use if foil seal appears damaged or opened.
3. Alternatively from the 0.8% Resolve Panel, other 3% antibody identification panels may be used if they are diluted to a 0.8% level with MTS Diluent 2 (see instructions below)
4. Tipmaster pipette and tips
5. MTS Incubator
6. MTS Centrifuge

C. Procedure- antibody identification testing process

1. Visually inspect each card before use. (see limitations above)
2. Label the MTS Anti-IgG card with appropriate identification and number of panel cell being tested. Using the box labeled "Resolve Panel A" label two IgG cards with the patient's name and the numbers 1-11 the last one is reserved for the auto control. Panel B is only necessary if multiple antibodies or questionable results are obtained from Panel A. If Panel A does not completely rule out an antibody, Panel B will be used. Specific cells may be chosen from Panel B or the complete panel can be tested. A repeated auto control is not necessary in Panel B.
3. Remove the foil seals from the gel card. Foil should be removed immediately before testing or within one hour of testing. Once opened, the gel may begin to dry out which could affect test results. Ensure that residual foil does not block the opening of any microtube after removal of foil.
4. Using the tipmaster pipetter, add 50 uL of each 0.8% antibody panel cells to the correctly labeled microtubes. Do not touch pipette to gel card. ***The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.*** .
5. Ortho recommends an autocontrol be run in parallel, add 50 uL of 0.8 % patient's cell to auto control labeled microtube. (See E. Preparing auto control procedure below)
6. Using the tipmaster pipette, add 25 uL of plasma to each microtube. ***Again, the pipette tip should not touch the gel card.***
7. Incubate at 37 degrees for 15 minutes.
8. Centrifuge the gel cards at the preset condition (895 +/- 26 rpms for 10 minutes).
9. Read both the front and the back of the microtube macroscopically.
10. Immediately grade and record results on appropriate panel sheet.
11. Ensure that the antigram sheet corresponds to the panel of cells by comparing the lot number on the antigram sheet to the lot number on the vials of panel cells. Check the dating of the panel as well.
12. Centrifuge the IgG card only one time. If problems occur during the centrifuge process, i.e., power outage, misbalanced centrifuge, repeat the entire process rather than just recentrifuging the card.

D. Quality Control

1. Check that the quality control and maintenance has been performed for the day of use. The clip board should have the daily surgiscreen quality results and the daily checks performed and initials.
2. Ortho recommends a periodic check of the panel cells using a weak antibody.
3. An annual check will be performed using a diluted commercial antibody.

E. Preparing a 0.8% suspension of antibody identification cells (for other than Resolve Panels)

1. Label plastic 75 x 13 tubes for panel cells.
2. Dispense one volume (suggested 100 uL) of each panel cell into each of the correctly labeled 75 x 13 tubes, add a small volume of MTS Diluent 2 to each test tube to increase the total volume.
3. Centrifuge to pack the red blood cells, one minute using the Immufuge II.
4. Decant the supernatant (a dry cell button is recommended).
5. Add two volumes (200 uL) of the MTS Diluent 2 to each tube.
6. Mix gently to resuspend. The final red blood cell suspensions should be approximately 0.8% and must be used within 24 hours.
7. Proceed with antibody identification process as in C. above.

F. Preparing an Auto Control

1. Label a 75 x 13 plastic tube with the patient's name.
2. Pipette 1.0 ml of MTS Diluent 2 into the test tube.
3. Add 10 uL of packed red blood cells from the sample to be tested.
4. Mix gently to resuspend. The final red blood cell suspension should be approximately 0.8% and must be used within 24 hours.
5. Ortho Resolve Panel A instructions recommend an auto "control of error" be performed in parallel. A positive reaction indicates patient abnormality which must be resolved before the test results can be interpreted.

G. Limitations

1. Erroneous results may occur if proper dilution and centrifugation procedures are not followed. This includes the correctly calibrated time, speed and angle of the centrifuge
2. False positive or negative 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 sample.
3. Rouleaux caused by plasma with abnormally high concentration of protein, such as patients on plasma expanders (most likely from the surgery department), or with multiple myeloma or Waldenstrom's macroglobulinemia may cause difficulties in Gel Test interpretations. False positive results or hazy reactions may occur with these samples but are rare.
4. Atypical gel reactions will be entered as "A" into the Wyndgate computer, and a manual tube panel (or sent out to a Reference lab) will be done.
5. Red blood cells that test as DAT positive should not be used.
6. The Anti-IgG card will not detect anti-C3 red blood sensitizations.
7. Optimal reaction conditions vary across antibody specificities. No single test method will detect all antibodies. In some low ionic strength test systems, certain antibodies, such as Anti-E and Anti-K, have been reported to be nonreactive.
8. There is the potential for IgM antibodies to react in the test.
9. False positive results may occur if a card that shows signs of drying is used in testing.
10. The Anti-H of Para-Bombay individuals may not be detectable via the gel method.
11. If the autocontrol is positive, this may mean there is an autoantibody. Consideration should be made to send the specimen out to Red Cross for identification. Repeating a tube screen with and then without LISS is another option.
12. Red blood cells must be suspended in MTS Diluent 2 or be a commercial 0.8% red blood cell in low ionic strength diluent specifically approved for use with the ID-Micro Typing System.

13. Variations in the red blood cell concentration can markedly affect the sensitivity of test results. If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ration. In addition, red blood cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When the red blood cells are too low in concentration, they become difficult to visualize and, in extreme cases, a weak positive can fail to be detected.
14. Irregular results may occur if fresh serum, fibrin or particulate matter in serum or plasma is present, or in cases where red cells stick to the sides of the microtube. Anomalous results (for example a line of red cells on the top of the gel) may be observed with serum samples and can be minimized by the use of EDTA plasma.
15. Due to complexities associated with the Duffy blood group system in the black population, it cannot be assumed that cells which are labeled Fy (a+b-) or Fy (a-b+) are homozygous for the Fya or Fyb antigens.
16. Antibodies to low-incidence antigens not present on the test cells will not be detected.
17. Do not add other potentiators to the gel test card.
18. For antibody detection and identification, different serological methods are optimal for different antibodies. No single antibody screening or identification method optimally detects all antibodies. In some low ionic strength test systems, certain Anti-E and Anti-K antibodies have been reported to be nonreactive. Full AHG crossmatches are required on all transfusions with positive screens.

V. INTERPRETATION

a. Grading Gel Test Reactions

1. ***0- 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.
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. Mixed field results will not be interpreted, the reactions will be documented, and a tube panel or results from a Reference lab will be used. Mixed field can occur from cold agglutinins, fibrin, autoantibodies or alloantibodies. Further investigation including dat testing, pre-warmed technique, tube panel, Reference laboratory shall be considered.

b. Problem Positives

1. Positive reactions in the auto control microtube may indicate the presence of an autoantibody. Clinical history regarding recent red blood cell transfusions may be helpful. Further testing including DAT and a repeat antibody panel using the tube method and or a

prewarmed technique may be needed. Perform a tube panel with LISS. If warm reactive antibodies or when a LISS dependent antibody or LISS enhanced cold reactive antibody is suspected, use albumin in the Tube method. See the "Antibody Panel Tube Method" policy for further instructions. If resolution is not found, the sample may need to be sent out for reference antibody ID testing.

2. If all cells are reactive, a high incidence antibody, multiple antibodies or a non-specific immune protein may be present. The specimen may need to be sent to the Red Cross for reference testing.
3. The use of plasma may fail to detect complement-dependent antibodies.

c. Panel Interpretation

1. Choose the first cell giving a negative reaction. At the top of the Antigram antigen master list, draw a slash through each antigen present on that cell. (the plus sign indicated the antigen for that column is present on the cell). Make one slash though all the antigens that gave a negative reaction for that row. For those antigens that show a dosage effect (all significant antigens except Kell) and the antigen is present in the double-dose state (homozygous allele- see below) a second slash can be made. Duffy antigens may not show dosage.
2. Continue for each row (1-11) for each negative reaction, making one cross for each negative single dose, and two cross offs for double dose negative reactions: *Homozygous versus Heterozygous Alleles/Dosing* Reaction strength of some antibodies may vary because of a phenomenon Known as dosage, in which antibodies reaction stronger (or only) with red Cells that posses a "double-dose" expression of the antigen. Rh (except D), Duffy, MNS and Kidd blood groups may demonstrate dosage.

3. Examples: { Jka+ Jkb+} does not exhibit double dosage (the alleles are heterozygous) {Jka + Jkb-} this shows a double dose of Jka (the alleles are homozygous) {C+ c-} this shows a double dose of C (the alleles are homozygous) {E+ e+} this does not exhibit double dosage (the alleles are heterozygous)
4. Circle the antigens that have no slashes.
5. Annotate in some manner those antigens having fewer than three slashes. Note: A negative reaction with a panel cell does not automatically rule out the presence of an antibody in the sample under test. Some antibodies may react weakly or be nonreactive with cells carrying only a single dose of the antigen, or have a lower frequency of the number of antigenic sites.
6. Antigens with three slashes indicate that corresponding antibody has been most probably ruled
   out.
   Note: In the routine patient care situation, it is not always necessary to rule out low incidence antigens such as C^w , Kp^a, or V. These antibodies are uncommon, and the corresponding antigens are present on the RBCs of less than 2% of the random population.
7. If only one antigen remains after excluding those antigens present on all nonreactive panel cells, and the pattern of the antigen matches the pattern of reactivity obtained, the specificity of the antibody is tentatively identified.
8. Statistics can be used for difficult situations where the antigen on a cell may be weakly expressed. Use of the following probability table is acceptable in identification of antibodies.

Probability Values For Selected Identification (AABB pg 474, 16th Edition)

The P value shown are the results of statistical tests that show the likelihood of a given set of results being due to chance alone. A P value of 0.05 or less is considered statistically valid. Note the number of positive and negative results can be interchanged.

9. Test selected cells from another Gel panel or can use tube panel cells using III.D above to prepare correct dilution of red cells, or can expired Gel panel to find selected cells.
10. Outdated Gel panel cells can be used for selecting cells after Resolve A and B are used for initial identification. (Caution: some antigens may deteriorate after prolonged storage.)
11. Perform antigen testing for the suspected antibody on the patient's cells.
12. If no identification is possible, further workup may be necessary including:
    *Call Pathologist in an urgent situation where transfusion is needed for patient safety

    *Refer specimen to reference lab (Call ARC reference lab and fill out Immunohematology Consultation Request, and Urgent Release of Test Results and redraw the proper number and types of tubes to send)

13. Panels are kept in the TS department and reviewed by Section head or designee.

14. Add on an antibody panel to your current Wyndgate order number. Add a line to the test grid (right click the mouse) and add the test ABID. Click on the PW button and Query button, and choose the correct patient and test form from the grid. Click on the RE button, enter the specimen number (BB ID) and enter the identified antibody at the interpretation box, save your results.

15. Identified antibody is noted in the Wyndgate computer system in the patient at a glance bar. ABY on the antibody panel will be in red if an antibody has been entered in the system. A history card will be filled out with the proper identification and kept in the file cabinet for possible downtime situations. (During computer downtime the manual file should be checked for each patient prior to transfusion to confirm no known antibody was missed.)

VI. REFERENCES

Ortho-Clinical Diagnostics, Inc. Procedures 6 and 8 version 5.0 (5-31-2010)
Antibody Detection Method, Antibody Identification Method (with Auto Control)
AABB Technical Manual, Sixteenth Edition, 2008
Ortho-Clinical Package Insert for Resolve A and B, May 2006

#Tested	#Positive	#Negative	*P Value*	Acceptance
5	3	2	0.100	No
6	4	2	0.067	No
7	5	2	0.048	Yes
7	4	3	0.029	Yes
8	7	1	0.125	No
8	6	2	0.036	Yes
8	5	3	0.018	Yes

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Creatinine Clearance	Policy #	CHEM2390
Responsible	Laboratory Director	Revised/Reviewed	12/15/2022~~11/1/20~~

I. PURPOSE

The determination of creatinine clearance is a measurement used for the early detection of renal failure. The rate at which creatinine is cleared from the blood by the kidneys via urine can be a significant indicator of the rate of loss of renal function. Creatinine is cleared only by glomerular filtration and is normally neither reabsorbed nor secreted by the tubules. Therefore, creatinine is an ideal substance for clearance measurement. It is a natural product of catabolism produced at a constant rate by an individual and is only eliminated by renal action.

II. POLICY

It is the policy of WCH to offer creatinine clearance measurement using a 24 hour urine specimen and a blood specimen collected during the urine collection period

III. PRINCIPLE

Beckman Coulter Synchron instrumentation uses a modified rate Jaffe method to measure the creatinine concentration in serum, plasma, and urine specimens. Creatinine combines with picrate in an alkaline solution to form a creatinine-pictrate complex which produces a red colored complex. The change of absorbance is at 520 nanometers is directly proportional to the creatinine concentration in the specimen.

IV. PROCEDURE

A. Specimen Collection

Serum or plasma and a 24 hr urine collection are used for analysis.
The serum/plasma specimen must be obtained within the 24 hr urine collection period.
Creatinine in serum or plasma is stable 7 days if refrigerated and indefinitely if frozen.
Creatinine in urine is stable 2-3 days at room temperature or 5 days refrigerated.

B. Testing

Serum and/or plasma and urine from a 24 hr collection are analyzed on either DxCi 600 instrument. The 24 hr urine volume is entered manually into the HMS computer. The patient height and weight and body surface area (determined from the nomogram on the following page or using the Body Surface Area Calculator) are entered manually into the HMS computer. The HMS computer is programmed to calculate the creatinine clearance using the following formula:

Bcr = Ucr(mg/dL) x Vol(mL/24hr) X 1.73
Pcr(mg/dL) x 1440min/24hr A

Bcr = Creatinine Clearance (serum/plasma cleared per standard body surface area)
Vol = Volume of urine excreted in 24 hrs
Ucr = Concentration of creatinine in urine
Pcr = Concentration of creatinine in plasma/serum
A = Body surface area in square meters

C. Results
Expected values = 75-115 mL/min (females)
85-125 mL/min (males)
* Creatinine clearance normally decreases with age, each decade of life accounting for a decrease of about 6.5 mL/min

D. Quality Control
Calibration is performed on the Beckman instruments as required using Aqua cal levels 1,2, & 3 on the DxCi 600. Refer to the Beckman Calibration Procedure for complete details. BioRad Unassayed Chemistry Controls Levels 1 & 2 and BioRad Urine Chemistry Control Levels 1 & 2 are run each day of use. See the Chemistry Quality Control Procedure for complete details.

E. Limitations of Procedure
The instrument will flag any specific malfunction's with an error message. Specimens with error messages should be held until investigation of the error is completed in accordance with the Beckman system manual.
Specimens exceeding linearity should be manually diluted and rerun. Plasma/serum specimens should be diluted 1:2 with purified water; urine specimens should be diluted 1:10 with saline diluent. The dilution factor should be entered when ordering the test. The results will be automatically corrected for the dilution and can be reported as they appear.

F. Remedial Action
If the accuracy of the test result is in doubt, rerun the QC.

G. Supplies
Supplies are stocked in the Chemistry Dept.
The Beckman Creatinine reagents are stored in at room temperature. They are on the shelves opposite the instruments. Open Aqua cal is stored at room temperature on the C1 bench. Unopened bottles are stored in the Isotemp refrigerator. The BioRad urine & chemistry controls are stored in the Isotemp refrigerator.

H. Infection Control
Gloves must be worn during testing.

V. REFERENCES

EBeckman Coulter LX20 & CX9 Operators Manual
1. Beckman Coulter Chemistry Information Manual
2. M. Bishop, J Duben-Von Laufen, E Fody, linicla Chemistry Principles, Procedures, Correlation. J>B> Lippencott Co, Philadelphia, PA, 1985, p430.

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Glucose Tolerance Test	Policy #	CHEM2391
Responsible	VP Ancillary Services	Revised/Reviewed	~~09/1/20~~10/31/2022

I. PURPOSE

Glucose tolerance testing is used in the diagnosis of clinical diabetes and gestational diabetes. There are three (3) concentrations of glucose tolerance beverages for use different situations.

It is estimated that 15.7 million people (5.9% of the population in the US) have diabetes. In 1995, diabetes was listed as the 7th leading cause of death on death certificates. It has also been observed that women with gestational diabetes (diabetes that arises during pregnancy) have a substantially increased likelihood of developing clinical diabetes. Gestational diabetes increases the risk of fetal death, neonatal respiratory distress, and obesity and diabetes in the offspring.

50 grams:	Used in 1 hr glucose challenge or 1 hour O'Sullivan gestational screening. This test should be performed between 24 and 28 weeks of gestation.
75 grams:	Used in glucose tolerance testing for pregnant adults and non-pregnant adults
100 grams:	Used in glucose tolerance testing for pregnant adults

The 1997 Guideline for Care in gestational diabetes recommends a 2 step method for testing. Whenever 2 values are abnormal, treatment for gestational diabetes is indicated. First a 50 gram glucose load screen is done. The screen is considered negative if the glucose is <140 mg/dL and positive if the glucose is >140mg/dL. A glucose between 140 & 190 requires 'step 2' - a 3hr glucose tolerance. A glucose >190mg/dL requires a fasting glucose to be done. A fasting value >95mg/dL is considered the second abnormal value. In this case, a 3hr 100 gram glucose tolerance test will not be performed.

II. POLICY

It is the policy of WCH to offer glucose tolerance measurement of blood samples. This policy is for Laboratory Technicians and Clinical Laboratory Scientists.

III. PRINCIPLE

Glucose is measured using an oxygen rate method. Oxygen is consumed at the same rate as glucose forms gluconic acid. The rate of reaction is measured across the glucose electrode.

IV. PATIENT PREPARATION

PATIENT PREPARATION

A. For the 2 hour and 3 hour GTT, the patient should be suggested on a diet consisting of at least 150 grams of carbohydrate per day for three days prior to the date of the test. Instruction sheets are provided to Doctor's offices.
B. The patient must be fasting for 8 hours but not more than 14 hours prior to the test and remain fasting during the entire period of the test; ONLY water is allowed during the test.

C. The patient should be encouraged to have adequate fluid intake (WATER ONLY) so as to avoid dehydration and to provide adequate urine flow.
D. The patient should not smoke and should not engage in any physical activity during the test. Encourage patients to remain in or near the lab.
E. Exceptions: Patients for the one (1) hour glucose challenge (50-gram) does not need to follow a special diet or be fasting prior to the test.

V. PROCEDURE

A. Obtain fasting blood glucose. Fasting glucose must be less than 127 before giving glucose solution. NOTE: It is acceptable to use Precision XceedPro results for the fasting glucose prior to getting the DXC instrument result, but the DXC instrument result is reported. If fasting glucose is greater than 126, notify ordering physician. Do not give glucose beverage.
B. For patients that would drink the 50 or 75 gram glucose beverage
    a. Administer test in the morning, when possible, and advise patient to remain quiet for the duration of the test
    b. For children, administer 0.175oz (1.75 grams) glucose per kilogram of body weight to 7.5 oz (75 grams).
    c. NOTE: Do not substitute 50 gram, 75 gram, or 100 gram beverage bottle if one is out or expired.
C. Blood samples must be centrifuged within 30 minutes of collection.
D. **One (1) Hour Glucose Challenge (50-gram)** – is performed to screen pregnant women for gestational diabetes.
    a. Order G1P50
        i. Collect a gray or green top tube
    b. Patient fasting is not required
    c. Check physician's order for any special instructions or exceptions
    d. Give patient a 50-gram bottle of glucose solution to drink
        i. Check expiration date on the bottle prior to giving it to the patient
        ii. Instruct the patient to consume the solution within 5 minutes
        iii. Instruct the patient not to eat or drink anything other than water during the 1 hour wait
        iv. Time the glucose blood draw for 1 hour after drinking the entire bottle of glucose
            i. If the patient finishes the glucose drink at 12:00, draw the blood sample at 13:00.
            ii. NOTE: Strongly suggest that the patient remains on the hospital premises until the entire procedure is completed due to possible reaction to the glucose and importance of collecting the blood sample exactly 1 hour after the glucose is consumed.
E. Standard Two (2) Hour Glucose Tolerance Test (75-gram) – is intended for non-pregnant patients.
    a. Order GLUFH
        i. Obtain a fasting blood specimen (first blood sample)
        ii. Collect a gray or green top tube.
        iii. NOTE: If fasting glucose is greater than 126, notify ordering physician. Do not give glucose beverage.
    b. Give patient a 75-gram bottle of glucose solution to drink
        i. Check expiration date on the bottle prior to giving it to the patient

ii. Instruct the patient to consume the solution within 5 minutes
iii. Instruct the patient that a second and third blood samples will be taken at 60 minutes and 120 minutes after consuming the glucose solution
iv. Instruct the patient not to eat or drink anything other than water during the 1 hour and 2 hour wait
v. Instruct the patient to notify the lab personnel if the patient vomits so testing can be stopped immediately
vi. Time the glucose blood draw for 1 hour and 2 hour after drinking the entire bottle of glucose
    i. If the patient finishes the glucose drink at 08:00, draw the following time:
        1. Draw blood sample at 09:00 (second sample, order GLU1H)
        2. Draw blood sample at 10:00 (third sample, order GLU2H)
    ii. NOTE: Strongly suggest that the patient remains on the hospital premises until the entire procedure is completed due to possible reaction to the glucose and importance of collecting the blood sample exactly 1 hour and 2 hour after the glucose is consumed.

F. Two (2) Hours Postprandial

a. Order 2HRPP
b. Obtain blood sample at exactly 2 hours after patient has eaten a meal
    i. Expected results: <180 mg/dL

G. **Two (2) Hour Gestational Glucose Tolerance Test (75-gram)** – is intended for pregnant patients who have a previous abnormal 50-gram challenge test.

a. Order GLUGF
    i. Obtain a fasting blood specimen (first blood sample)
    ii. Collect a gray or green top tube.
    iii. iii. NOTE: If fasting glucose is greater than 126, notify ordering physician. Do not give glucose beverage.
b. Give patient a 75-gram bottle of glucose solution to drink
    i. Check expiration date on the bottle prior to giving it to the patient
    ii. Instruct the patient to consume the solution within 5 minutes
    iii. Instruct the patient that a second and third blood samples will be taken at 60 minutes and 120 minutes after consuming the glucose solution
    iv. Instruct the patient not to eat or drink anything other than water during the 1 hour and 2 hour wait
    v. Instruct the patient to notify the lab personnel if the patient becomes ill and/or vomits during any part of these tests, the test must be stopped immediately
        i. Inform the ordering/requesting physician and instruct patient to return
    vi. Time the glucose blood draw for 1 hour and 2 hour after drinking the entire bottle of glucose
        i. If the patient finishes the glucose drink at 08:00, draw the following time:

1. Draw blood sample at 09:00 (second sample, order 75GLUG1)
2. Draw blood sample at 10:00 (third sample, order 75GLUG2)

ii. NOTE: Strongly suggest that the patient remains on the hospital premises until the entire procedure is completed due to possible reaction to the glucose and importance of collecting the blood sample exactly 1 hour and 2 hour after the glucose is consumed.

H. Three (3) Hour Gestational Glucose Tolerance Test (100gram) – is intended for pregnant patients who have a previous abnormal 50-gram challenge test but may be used for nonpregnant patients if request.

1. Order GLUGF
    a. Obtain a fasting blood specimen (first blood sample)
    b. Collect a gray or green top tube.
    c. NOTE: If fasting glucose is greater than 126, notify ordering physician. Do not give glucose beverage.
2. Check physician's order for any special instructions or exceptions
    a. Physician will indicate number of hours, and may indicate 5 hours glucose challenge. Order GLUG4 and GLUG5 if needed.
3. Give patient a 100-gram bottle of glucose solution to drink
    a. Check expiration date on the bottle prior to giving it to the patient
    b. Instruct the patient to consume the solution within 5 minutes
    c. Instruct the patient that a second, third and fourth blood samples will be taken at 60, 120, and 180 minutes after consuming the glucose solution
    d. Instruct the patient not to eat or drink anything other than water until the post-challenge specimens have been collected
    e. Instruct the patient to notify the lab personnel if the patient becomes ill and/or vomits during any part of these tests, the test must be stopped immediately
        i. Inform the ordering/requesting physician and instruct patient to return
    f. Time the glucose blood draw for 1 hour , 2 hour and 3 hour after drinking the entire bottle of glucose
        i. If the patient finishes the glucose drink at 08:00, draw the following time:
            i. Draw blood sample at 09:00 (second sample, order GLUG1)
            ii. Draw blood sample at 10:00 (third sample, order GLUG2)
            iii. Draw blood sample at 11:00 (fourth sample, order GLUG3)
        ii. NOTE: Strongly suggest that the patient remains on the hospital premises until the entire procedure is completed due to possible reaction to the glucose and importance of collecting the blood sample exactly 1, 2, and 3 hours after the glucose is consumed.

I. **Five (5) Hour Glucose Tolerance Test (75-gram)** – is intended for hypoglycemia patients

1. Order GLUFH
    a. Obtain a fasting blood specimen (first blood sample)
    b. Collect a gray or green top tube.
    c. NOTE: If fasting glucose is greater than 126, notify ordering physician. Do not give glucose beverage.
2. Give patient a 75-gram bottle of glucose solution to drink

a. Check expiration date on the bottle prior to giving it to the patient
b. Instruct the patient to consume the solution within 5 minutes
c. Instruct the patient that a second and third blood samples will be taken at 60, 120, 180, 240, and 300 minutes after consuming the glucose solution
d. Instruct the patient not to eat or drink anything other than water during the 1 hour and 2 hour wait
e. Instruct the patient to notify the lab personnel if the patient vomits so testing can be stopped immediately
f. Time the glucose blood draw for 1, 2, 3, 4, 5 hours after drinking the entire bottle of glucose
    i. If the patient finishes the glucose drink at 08:00, draw the following time:
        i. Draw blood sample at 09:00 (second sample, order GLU1H)
        ii. Draw blood sample at 10:00 (third sample, order GLU2H)
        iii. Draw blood sample at 11:00 (fourth sample, order GLU3H)
        iv. Draw blood sample at 12:00 (fifth sample, order GLU4H)
        v. Draw blood sample at 13:00 (sixth sample, order GLU5H)
    ii. NOTE: Strongly suggest that the patient remains on the hospital premises until the entire procedure is completed due to possible reaction to the glucose and importance of collecting the blood sample exactly 1, 2, 3, 4, and 5 hours after the glucose is consumed.

VI. RESULTS

For non-pregnant adults, a 1, 2, 3, 4, or 5 hour glucose tolerance test may be ordered. A 2 hour GTT is considered standard. Normal ranges are as follows:

1 hour challenge = 120-139 mg/dL
Fasting glucose = 70-110 mg/dL
1 hour glucose = 120-170 mg/dL
2 hour glucose = 70-120 mg/dL
3 hour glucose = 67-107 mg/dL
4 hour glucose = 67-107 mg/dL
5 hour glucose = 67-107 mg/dL

Gestational ranges are as follows:

50g challenge = < 140 mg/dL
Fasting glucose = </= 94 mg/dL
1 hour glucose = </= 179 mg/dL
2 hour glucose = </= 154 mg/dL
3 hour glucose = </= 139 mg/dL

VII. QUALITY CONTROL

Glucose QC is run daily with the AM & PM control runs.

VIII. LIMITATIONS

1. Glucose solution should be consumed within 5 minutes.
2. Any vomiting or diarrhea negates the test.
3. Smoking, stress, steroid use, oral contraceptives, diuretics, and antihypertensive drugs may interfere with the glucose testing.

IX. REMEDIAL ACTION

If the accuracy of the test result is in doubt, rerun the QC.

X. SUPPLIES

Supplies are stocked in the Chemistry Dept.
The Glucose reagents are stored in the Jordan double refrigerator..
The BioRad controls are stored in the Isotemp refrigerator.

XI. INFECTION CONTROL

Gloves must be worn during testing.

XII. REFERENCES

1. Diagnosis and Management of Gestational Diabetes: R.M. Ramus, J.L. Kitzmiller; Diabetes Reviews: Vol2; Winter 1994.
2. The Sweet Success Guidelines for Care: P. Payne-Zajac; Lecture
3. Diagnosing Diabetes; B. Chapman; CAP Today; March 1998

XIII. REFERENCES

N/A

XIV. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Procalcitonin (PCT)	Policy #	CHEM2392
Responsible	Laboratory Director	Revised/Reviewed	~~1/2021~~12/15/2022

I. PURPOSE

INTENDED USE

The Access PCT assay is a paramagnetic, chemiluminescent immunoassay for in vitro quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin and EDTA) using the Access Immunoassay Systems. Measurement of PCT in conjunction with other laboratory findings and clinical assessments aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

SUMMARY AND EXPLANATION

Sepsis is a systemic inflammatory response to infection that can result in a number of life-threatening conditions including organ dysfunction.1 Septic shock is a subset of sepsis in which circulatory and cellular metabolism abnormalities are profound enough to substantially increase mortality.2,3

Despite advances in modern medicine like vaccines, antibiotics and advanced acute care, sepsis is the primary cause of death from infection, causing an estimated 5.3 million deaths worldwide each year.4 Early identification and appropriate management in the initial hours after sepsis develops has been found to improve outcomes for patients.

Procalcitonin (PCT), a prohormone of calcitonin, is a protein consisting of 116 amino acids with a molecular weight of approximately 13 kDa.5 In healthy individuals, PCT is produced in the thyroid C-cells and is subsequently converted into calcitonin in the thyroid with almost no PCT entering the circulation. PCT levels in healthy individuals are typically less than 0.1 ng/mL.5,6

In individuals with systemic inflammation or bacterial infections, PCT levels rise in the circulation in response to bacterial endotoxins and inflammatory cytokines. PCT levels show an increase in levels within 2-6 hours and peak within 6-12 hours of infection.5,6,7,8 PCT levels have been found to correlate with the severity of bacterial infections and also with the probability of a positive blood culture, making it a clinically useful marker in the assessment of patients with possible sepsis or septic shock.1,9,10

Moreover, studies have found that PCT release is blocked by cytokines that are characteristically present in the immune response to viral infections. For this reason, PCT is more specific to bacterial infections, and can aid in the differential diagnosis between nonbacterial illnesses and bacterial illnesses and sepsis.9 In circulation, PCT has a half-life of 25-30 hours when controlled by the host immune system or appropriate treatment.5,8

PCT results may become elevated by causes other than systemic bacterial infection, including burns, trauma, autoimmune disorders or prolonged cardiogenic shock.6 Therefore, PCT should not be used alone but always in conjunction with patient history and clinical signs and symptoms.

METHODOLOGY

The Access PCT assay is a sequential two-step immunoenzymatic (“sandwich”) assay. Monoclonal anti-PCT antibody conjugated to alkaline phosphatase is added to a reaction vessel along with a surfactant-containing buffer and sample. After a short incubation, paramagnetic particles coated with monoclonal anti-PCT antibody are added. The PCT binds to the anti-PCT antibody on the solid phase, while the anti-PCT antibody-alkaline phosphatase conjugate reacts with different antigenic sites on the PCT molecules.
After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of procalcitonin in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

II. POLICY

It is the policy of WCH to offer Procalcitonin testing. PCT reagent, when used in conjunction with the Access Immunoassay Systems and PCT calibrator set, is intended for quantitative determination of procalcitonin (PCT) levels in human serum and plasma (lithium heparin).

III. SPECIMEN

SPECIMEN STORAGE AND STABILITY

Stability				
Specimen	**Type**	**20°C to 25°C (hours)**	**2°C to 10°C hours**	**-30°C to -15°C (days)**
Plasma	Lithium heparin	16	48	75

1. Do not thaw samples more than 3 times.
2. For serial determinations on the same patient, the same specimen type should always be used.
3. In general, grossly hemolyzed, icteric, and lipemic samples are not acceptable.

Specimen Collection and Preparation

1. The role of preanalytical factors in laboratory testing has been described in a variety of published literature.11 To minimize the effect of preanalytical factors observe the following recommendations for handling and processing blood samples:12
    a. Collect all blood samples observing routine precautions for venipuncture.
        i. Follow blood collection tube manufacturer’s recommendations for centrifugation.
        ii. Ensure residual fibrin and cellular matter has been removed prior to analysis.
    b. Allow samples to clot completely before centrifugation in a vertical, closure-up position.
        i. Nonanticoagulated tubes containing gel separator should be stored in an upright position as soon as the mixing is complete.

ii. Precentrifugation serum/cells contact time is according to tube manufacturer's recommendations. Clotting may be slowed at cooler temperatures or if the patient is on anticoagulant therapy.

2. Each laboratory should determine the acceptability of its own blood collection tubes and separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.

II. REAGENTS

CONTENTS

Access PCT Reagent Pack

Cat. No. C53987: 100 determinations, 2 packs, 50 tests/pack

Well	Ingredients
R1a:	Dynabeads* paramagnetic particles coated with mouse anti-human procalcitonin monoclonal antibody in a TRIS buffer with surfactant, protein (bovine), ≤ 0.1% sodium azide, and 0.1% ProClin** 300
R1b:	0.10 N Sodium Hydroxide
R1c:	MOPS Buffer with surfactant and protein (bovine, murine), ≤ 0.1 % sodium azide, and 0.1% ProClin 300
R1d:	Rat anti-procalcitonin recombinant alkaline phosphatase conjugate in a MOPS buffer with surfactant and protein (bovine, murine, recombinant), ≤ 0.1% sodium azide, and 0.1% ProClin 300

*Dynabeads is a registered trademark of Dynal A.S., Oslo, Norway.
**ProClin™ is a trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow.

WARNING AND PRECAUTIONS

• For in vitro diagnostic use.

• Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices13, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.

• For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

CAUTION
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

PCT Particles (Compartment R1a)

WARNING

H317	May cause an allergic skin reaction.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
	reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

NaOH for PCT (Compartment R1b)

DANGER

H314	Causes severe skin burns and eye damage.
P280	Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or

		doctor/physician.
		Sodium Hydroxide 0.1 - 1%
PCT Ancillary Reagent (Compartment R1c)	WARNING	
		
	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		4-Morpholinepropanesulfonic Acid 1 - 5%
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
PCT Conjugate (Compartment R1d)	WARNING	
		
	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		4-Morpholinepropanesulfonic Acid 1 - 5%

reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access PCT Calibrators Provided at zero and approximately 0.8, 5, 10, 25, 50 and 100 ng/mL (µg/L). Cat. No. C53986
2. Quality Control (QC) materials: commercial control material.
3. Access Substrate Cat. No. 81906
4. Access 2, UniCel DxC 600i: Access Wash Buffer II, Cat. No. A16792 UniCel DxI 600, UniCel DxI 800, UniCel DxC 880i, UniCel DxC 860i, UniCel DxC 680i, UniCel DxC 660i: UniCel DxI Wash Buffer II, Cat. No. A16793

REAGENT PREPARATION

Provided ready to use.

REAGENT STORAGE AND STABILITY

Stability	
Unopened at 2°C to 10°C	Up to stated expiration date
After opening at 2°C to 10°C	42 days

- Store upright.
- Refrigerate at 2°C to 10°C for a minimum of two hours before use on the instrument.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., a broken elastomer), discard the pack.
- Discard reagent if any discoloration is observed.
- Do not freeze.

III. CALIBRATION

CALIBRATION INFORMATION

An active calibration curve is required for all tests. For the Access PCT assay, calibration is required every 42 days. Refer to the appropriate system manuals and/or Help system for information on calibration method, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Access PCT Calibrators
Cat. No. C53986, S0-S6, 2 mL/vial

- Provided lyophilized.

- Lyophilized calibrators are stable until the expiration date stated on the label when stored at 2°C to 10°C.
- Using a volumetric pipet or equivalent, reconstitute each vial using 2.0 mL distilled water. Allow 30 minutes for dissolution.
- Mix contents thoroughly by gently inverting before use.
- Use reconstituted calibrators within 4 hours when stored at 20°C to 25°C. Otherwise, freeze at -30°C to -15°C for up to 90 days.
- Thaw at room temperature. Mix contents thoroughly by gently inverting before use. Avoid bubble formation.
- Do not thaw calibrators more than 3 times.
- Signs of possible deterioration are quality control values out of range or failure of calibrators to completely reconstitute.
- Refer to calibration card for exact concentrations.

IV. QUALITY CONTROL

QC material for PCT - Lypochek Specialty immunoassay QC stored in Chem Ref#1 (top right shelf)

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.

Lypochek Specialty Immunoassay QC are ran at 11 am daily in Access-A by the day shift Chemistry CLS

Storage and Stability: This product will be stable until the expiration date when stored unopened at 2 to 8°C

Reconstituted and Refrigerated: After reconstitution and storing tightly capped at 2 to 8°C, this product is stable for 3 days for Procalcitonin.

Reconstitution Instruction: Using a volumetric pipet, reconstitute each vial with 2.0 ml of distilled or deionized water. Allow this product to stand for approximately 15 minutes swirling occasionally. Before sampling, gently swirl the vial several times to ensure homogeneity. Store the reconstituted product at 2 to 8°. Allow it to reach room temperature (18 to 25°C) before use. After use, promptly replace stopper and return to the refrigerator.

Limitations:

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the reconstituted product, discard the vial.
3. This product is not intended for use as a standard.

V. TESTING PROCEDURE(S)

PROCEDURE

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.

a. The system default unit of measure for sample results is ng/mL. To change sample reporting units to µg/L, refer to the appropriate system manuals and/or Help system. To manually convert concentrations to µg/L, multiply ng/mL by multiplication factor 1.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use thirty-five (35) µL of sample for each determination in addition to the sample container and system dead volumes when requesting the Access PCT assay. Use thirty (30) µL of sample in addition to the sample container and system dead volumes for each determination run with the special dilution feature (test name: PrCTd). Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.
a. Select PrCT as the test name for assaying samples containing procalcitonin concentrations up to the concentration of the Access PCT S6 calibrator.
b. Use the special dilution feature (test name: PrCTd) for assaying samples containing PCT concentrations greater than the Access PCT S6 calibrator.

VI. LIMITATIONS

1. Not indicated to be used as an aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time.
2. Not indicated to be used as an aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary diseases (AECOPD) in an inpatient setting or an emergency department.
3. Not indicated to be used as an aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis or other conditions.
4. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce human anti-animal antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other antibodies such as human anti-goat antibodies may be present in patient samples.14,15 Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
5. Other potential interferences in the sample could be present and may cause erroneous results in immunoassays. Some examples that have been documented in literature include rheumatoid factor, fibrin, endogenous alkaline phosphatase, exogenous alkaline phosphatase (e.g. asfotase alfa), and proteins capable of binding to alkaline phosphatase. Carefully evaluate results if the sample is suspected of having these types of interferences.16,17
6. The Access PCT assay is not intended to be used in isolation. The Access PCT results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information. In cases where the laboratory results do not agree with the clinical picture or history, additional tests should be performed.
7. Elevated PCT levels may be seen in conditions other than systemic bacterial infection. These may include but are not limited to polytrauma, burns, major surgery, and prolonged or cardiogenic shock.6 In addition, certain patient characteristics including, renal insufficiency or failure, may

impact procalcitonin levels and should be considered as potentially confounding clinical factors when evaluating PCT results.
8. PCT levels may not be elevated in patients infected by certain atypical pathogens, such as Chlamydophila pneumoniae and Mycoplasma pneumoniae.18
9. The safety and performance of PCT-guided therapy for individuals younger than 18 years of age, pregnant women, immunocompromised individuals, or those on immunomodulatory agents, was not formally analyzed in the supportive clinical trials.
10. Values obtained by different PCT assay methods may differ and should not be used interchangeably.
11. The Access PCT assay does not demonstrate any “hook” effect up to 5,000 ng/mL.

VII. RESULT INTERPRETATION

Test results are determined automatically by the system software. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

VIII. REPORTING RESULTS

Samples can be accurately measured within the analytical range of 0.05 ng/mL to the highest calibrator value (approximately 100 ng/mL).
• If a sample contains less than 0.05 ng/mL, report the result as < 0.05 ng/mL.
• If a sample contains more than the stated value of the highest Access PCT Calibrator (S6), report the result as greater than that value (i.e., > 100 ng/mL). Alternatively, use one of the dilution options below:
Dil-PCT Special Dilution Feature for use on Access 2 and UniCel DxI systems:
Samples containing PCT concentrations greater than the concentration of the PCT S6 calibrator can be processed using the Special Dilution Feature (test name: PrCTd). The Special Dilution Feature automates the dilution process, using one volume of sample with nine volumes of Wash Buffer II, allowing samples to be quantitated up to approximately 1,000 ng/mL [1,000 µg/L]. The system reports the results adjusted for the dilution.
Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.

IX. EXPECTED RESULTS

1. WCH Reference range is <0.1 ng/ml
2. PCT concentrations were measured in 202 adult human serum samples from a population of approximately equal numbers of apparently healthy male and female subjects greater than or equal to 21 years of age. Samples were analyzed at an external site using the Access PCT assay on the Access 2 Immunoassay System following the CLSI EP28-A3c19 guideline. The obtained results are shown in the following table:

Sample Size	Median	95% Upper Reference Interval (ng/mL)
202	0.025 ng/mL	0.065

Interpretation of PCT results for risk assessment for progression to severe sepsis and septic shock.

The Access PCT assay is only intended to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock. The interpretation of PCT results are as follows:

PCT Concentration (ng/mL or µg/L)	Interpretation
< 0.5	Low risk of severe sepsis and/or septic shock
> 2.0	High risk of severe sepsis and/or septic shock

Concentrations under 0.5 ng/mL do not exclude local infections or systemic infections in their initial stages (e.g., under six hours from onset of illness).20 PCT concentrations between 0.5 and 2.0 ng/mL should be interpreted with consideration of the patient's history. In this range, it is recommended to retest PCT within 6 to 24 hours.20

X. PERFORMANCE CHARACTERISTICS

Data provided in this section are representative of Access PCT performance on the Access 2 and UniCel DxI Immunoassay Systems. Performance obtained in individual laboratories may vary.

METHODS COMPARISON

A correlation study using human serum specimens (n = 207) was performed. The specimens were tested using three Access 2 Immunoassay Systems and compared to values obtained with the VIDAS® B·R·A·H·M·S PCT®† assay on the VIDAS®. The results were evaluated using Passing-Bablok analysis following CLSI EP09c guideline.21 The data is summarized below.

N	Range of Observations (ng/mL)	Intercept [95% CI]	Slope [95% CI]	Correlation Coefficient (r)
207	0.06 - 86.71	0.02 [0.00 - 0.04]	0.96 [0.94 - 0.99]	0.99

A concordance analysis between the two assays was also performed with cut-off values of 0.5 ng/mL and 2.0 ng/mL:

	VIDAS® B·R·A·H·M·S PCT®†		
Access PCT	≤ 0.5 ng/mL	> 0.5 ng/mL	Total
≤ 0.5 ng/mL	78	0	78
> 0.5 ng/mL	5	124	129
Total	83	124	207

	VIDAS® B·R·A·H·M·S PCT®†		
Access PCT	≤ 2.0 ng/mL	> 2.0 ng/mL	Total
≤ 2.0 ng/mL	122	2	124

	VIDAS® B·R·A·H·M·S PCT®†		
> 2.0 ng/mL	2	81	83
Total	124	83	207

The percentage of concordance between the two assays for the cut-offs of 0.5 and 2.0 ng/mL were 97.6% and 98.1%, respectively.

Concordance at Clinical Decision Points				
	VIDAS® B·R·A·H·M·S PCT®†			
Access PCT	≤ 0.5	> 0.5 to ≤ 2.0 ng/mL	> 2.0 ng/mL	Total
≤ 0.5	78	0	0	78
> 0.5 to ≤ 2.0 ng/mL	5	39	2	46
> 2.0 ng/mL	0	2	81	83
Total	83	41	83	207

†VIDAS® is a registered trademark of bioMérieux SA. B·R·A·H·M·S PCT® is a registered trademark of B·R·A·H·M·S GmbH.

XI. LINEARITY

The Access PCT assay demonstrated acceptable linearity throughout the analytical measuring range of 0.05 ng/mL to approximately 100 ng/mL.
The Access PCT assay was designed to be linear, with a maximum deviation from linearity of ≤ 10% for values > 0.150 ng/mL and ≤ 0.012 ng/mL for values ≤ 0.150 ng/mL.
In one study based on CLSI EP06-A22, one high sample and one low sample were mixed to make eight sample concentrations evenly distributed across the analytical measuring range. Four replicates of the six mixed samples, eight replicates of the low sample and four replicates of the high sample were tested on one reagent lot on multiple Access Immunoassay Systems

The obtained results, analyzed using a cubic regression method, are summarized in the table below:

Linearity Analysis (Full Range of Assay)						
Dilution (%)	**Expected Concentration (ng/mL)**	**Predicted Observed Linear Concentration (ng/mL)**	**Predicted Observed Non-Linear (Cubic) Concentration (ng/mL)**	**Predicted Difference (ng/mL)**	**Predicted Deviation from Linearity (%)**	**Criteria**
0	0.006	0.006	0.006	0.000	N/A	≤ ± 0.012 ng/mL
14.3	14.976	15.954	15.602	-0.352	-2	≤ ± 10%
28.6	29.945	31.901	32.405	0.504	2	≤ ± 10%
42.9	44.915	47.849	49.540	1.691	4	≤ ± 10%
57.1	59.884	63.796	66.132	2.335	4	≤ ± 10%
71.4	74.854	79.744	81.304	1.560	2	≤ ± 10%
85.7	89.823	95.691	94.180	-1.511	-2	≤ ± 10%
100	104.793	111.639	103.886	-7.754	-7	≤ ± 10%

In a second study conducted with samples covering the low range of the assay, one high sample and one low sample were mixed to make ten sample concentrations evenly distributed between 0.007 ng/mL and approximately 3 ng/mL. Four replicates of the eight mixed samples, eight replicates of the low sample and four replicates of the high sample were tested on one reagent lot on multiple Access Immunoassay Systems. The obtained results, analyzed using a cubic regression method, are summarized in the table below:

Linearity Analysis (Low Range of Assay)						
Dilution (%)	**Expected Concentration (ng/mL)**	**Predicted Observed Linear Concentration (ng/mL)**	**Predicted Observed Non-Linear (Cubic) Concentration (ng/mL)**	**Predicted Difference (ng/mL)**	**Predicted Deviation from Linearity (%)**	**Criteria**
0	0.007	0.007	0.007	0.000	0	≤ ± 0.012 ng/mL
6.25	0.184	0.184	0.180	-0.004	-2	≤ ± 10%
12.5	0.361	0.360	0.353	-0.007	-2	≤ ± 10%

Linearity Analysis (Low Range of Assay)						
Dilution (%)	Expected Concentration (ng/mL)	Predicted Observed Linear Concentration (ng/mL)	Predicted Observed Non-Linear (Cubic) Concentration (ng/mL)	Predicted Difference (ng/mL)	Predicted Deviation from Linearity (%)	Criteria
25	0.714	0.712	0.703	-0.009	-1	≤ ± 10%
37.5	1.068	1.064	1.056	-0.008	-1	≤ ± 10%
50	1.421	1.417	1.413	-0.004	0	≤ ± 10%
62.5	1.775	1.769	1.774	0.005	0	≤ ± 10%
75	2.128	2.121	2.138	0.017	1	≤ ± 10%
87.5	2.482	2.474	2.507	0.033	1	≤ ± 10%
100	2.835	2.826	2.879	0.053	2	≤ ± 10%

IMPRECISION

The Access PCT assay exhibits total imprecision of ≤ 8.0% CV at concentrations ≥ 0.150 ng/mL, and standard deviation (SD) ≤ 0.012 ng/mL at concentrations < 0.150 ng/mL.

The Access PCT assay exhibits within run imprecision of ≤ 6.0% CV at concentrations ≥ 0.150 ng/mL, and a standard deviation (SD) ≤ 0.009 ng/mL at concentrations < 0.150 ng/mL.

A study was performed using three commercially available controls and seven serum samples run over 20 days, 2 runs per day in replicates of 2, for a total of 80 replicates per sample. The study utilized three reagent lots, three calibrator lots and multiple calibrations on an Access Immunoassay System. The following results were calculated based on CLSI EP05-A323 guidelines.

		Within-Run (Repeatability)		Between-Run		Between-Day		Within Lab (Total Imprecision)	
Sample	Grand Mean (ng/mL) (N = 80)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)
QC 1	0.68	0.013	1.9	0.014	2.1	0.015	2.2	0.024	3.6
QC 2	2.15	0.040	1.9	0.056	2.6	0*	N/A	0.069	3.2

		Within-Run (Repeatability)		Between-Run		Between-Day		Within Lab (Total Imprecision)	
Sample	Grand Mean (ng/mL) (N = 80)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)
QC 3	20.65	0.333	1.6	0.531	2.6	0.228	1.1	0.667	3.2
Sample 1	0.090	0.003	3.2	0.002	2.7	0.005	5.8	0.006	7.2
Sample 2	0.18	0.006	3.2	0.003	1.7	0.008	4.3	0.010	5.6
Sample 3	0.27	0.008	2.8	0.003	1.0	0.009	3.2	0.012	4.4
Sample 4	0.43	0.011	2.6	0.014	3.3	0.016	3.8	0.024	5.7
Sample 5	1.41	0.039	2.8	0.034	2.4	0.048	3.4	0.070	5.0
Sample 6	7.59	0.175	2.3	0.121	1.6	0.239	3.2	0.320	4.2
Sample 7	76.31	1.753	2.3	1.773	2.3	1.452	1.9	2.885	3.8

* Default value when estimated variance was negative.

Total Error (TE) including estimated bias relative to the VIDAS® B·R·A·H·M·S PCT®† assay was determined for the lower end of the measuring range. The Passing-Bablok and Weighted Deming regression slope and intercept values were used to calculate estimated bias at each concentration listed in the table below following CLSI guideline EP09c, 3rd Edition.21 A precision profile model was fit to the precision estimates obtained from the within-laboratory imprecision study following CLSI guideline EP05-A3.23 The bias and precision profile estimates were combined using the Westgard model to calculate the total error estimates in the table below.

Percent Total Error Estimates Based on Bias Estimates Using Weighted Deming

Concentration (ng/mL)	Bias (%)	CV (%)	Total Error (%)
0.5	0.6	4.5	9.4

Concentration (ng/mL)	Bias (%)	CV (%)	Total Error (%)
2	0.7	4.2	8.9

Percent Total Error Estimates Based on Bias Estimates Using Passing-Bablok

Concentration (ng/mL)	Bias (%)	CV (%)	Total Error (%)
0.5	-0.6	4.5	9.4
2	-3.1	4.2	11.3

† VIDAS® is a registered trademark of bioMérieux, SA. B·R·A·H·M·S PCT® is a registered trademark of B·R·A·H·M·S GmbH.

Interfering Substances

Serum samples containing PCT concentrations of approximately 0.25, 0.5, 2.0 and 80 ng/mL were spiked with the concentrations of the substances below and run on a single Access Immunoassay System. Values were calculated as described in CLSI EP07-A3.24 Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). Of the compounds tested, none were found to cause significant interference as defined by a shift in concentration greater than 10% using the test concentrations indicated in the table below.

Substance	Interferent Concentration Tested
Acetaminophen	20 mg/dL
Acetylsalicylic acid	100 mg/dL
Azithromycin	1.20 mg/dL
Bilirubin (conjugated and unconjugated)	40 mg/dL
Caffeine	6.0 mg/dL
Cefotaxime/Cefotaxin	90 mg/dL
Celecoxib	24 mg/dL
Cetirizine HCl	0.36 mg/dL
Dextromethorphan	0.14 mg/dL
Dobutamine	1.12 mg/dL
Dopamine	13 mg/dL
Doxycycline	5.0 mg/dL

Substance	Interferent Concentration Tested
Epinephrine (adrenaline)	0.18 mg/dL
Ethanol	400 mg/dL
Fentanyl	1.0 mg/dL
Furosemide	5.98 mg/dL
Hemoglobin	400 mg/dL
Heparin	8,000 IU/L
Human Serum Albumin	12 g/dL
Ibuprofen	50 mg/dL
Imipenem	18 mg/dL
Levofloxacin	1.75 mg/dL
Loratadine	0.03 mg/dL
Naproxen	50 mg/dL
Nicotine	0.1 mg/dL
Noradrenaline	0.2 mg/dL
Oxymetazoline HCl	0.009 mg/dL
Phenylephrine	0.018 mg/dL
Prednisolone	0.3 mg/dL
Salmeterol	0.006 mg/dL
Theophylline	10 mg/dL
Tiotropium	0.0022 mg/dL
Triglycerides (intralipid)	3,000 mg/dL
Vancomycin	100 mg/dL

The Access PCT assay does not utilize biotin-streptavidin particle chemistry; as a result, it is not susceptible to biotin interference.

CROSS REACTIVITY

A study was performed to evaluate the potential cross-reactivity of the Access PCT assay with other substances that are similar in structure to procalcitonin. Serum samples containing procalcitonin concentrations of approximately 0.25, 0.5 and 2.0 ng/mL were spiked with the concentration of the substance listed below and run on the Access Immunoassay System. Values were calculated as described in CLSI EP07-A3.24 There was no significant cross-reactivity observed, as defined by a shift in dose greater than 10%, when the following substances were tested at the concentrations indicated in the table below.

Substance	Concentration
Human Calcitonin	60 ng/mL
Human Katacalcin	10 ng/mL
Human α-CGRP	10 µg/mL
Human β-CGRP	10 µg/mL

SENSITIVITY

Parameter	Total Samples	Total Replicates per Study	Total Runs Per Study	Claim (ng/mL)
Limit of Blank (LoB) – highest measurement result that is likely to be observed in a blank sample.	4	120	6	0.005
Limit of Detection (LoD) – the lowest concentration of analyte that can be consistently detected.	10	450	5	0.01
Limit of Quantitation (LoQ) ≤ 20% Total CV – lowest amount of a measurand in a material that can be quantitatively determined with stated accuracy.	10	450	5	0.02

Results were calculated using a protocol based on CLSI EP17-A225 with three reagent lots and one calibrator lot on multiple Access Immunoassay Systems for a total of three studies

XII. REFERENCES

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WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	Chemistry Instrument Correlation	Policy #	CHEM2393
Responsible	Laboratory Director	Revised/Reviewed	12/15/2022~~12/2020~~

I. PURPOSE

To evaluate the performance of chemistry test results done on multiple instruments.

II. POLICY

It is the policy of WCH to compare test results of tests performed on multiple instruments to assure consistency and accuracy of reported results. Tests are to be compared at least 2 times each year.

Testing on multiple instruments must conform to a standard that assures patient safety and consistent tests values on each instrument.

III. DEFINITIONS

N/A

IV. PROCEDURE

A. Frequency
1. A minimum of 20 specimens per test must be compared on each instrument per year.
2. Testing must be performed at least twice a year.

B. Testing
1. Run specimens on each instrument for each test on the same day.
2. Run specimens concurrently or within 1 hour of testing on each instrument.
3. Use fresh patient specimens or proficiency specimens.

C. Results
1. Record results and enter into evaluation program on the computer.
2. Computer program will calculate means, SDs, and RRs.

D. Quality Control
1. Daily quality control must be run on each instrument per QC policy.

E. Limitations of Procedure
1. Results from each instrument should meet CLIA Allowable Total Error Limits.
2. Where CLIA limits are unavailable, results should compare within WCH QC limits.

F. Remedial Action
1. If the accuracy of the test results fail to meet specifications, calibration verification criteria should be followed.
2. Instruments should be recalibrated and quality control rerun. Repeat specimens and verify compliance.
3. Use of tests and/or instruments that do not meet criteria must be discontinued on the secondary instrument.

V. REFERENCES

N/A

VI. STAKEHOLDERS

N/A

WATSONVILLE
COMMUNITY HOSPITAL

Policy Title	D-10 HEMOGLOBIN A1c BY BIORAD	Policy #	CHEM2589
Responsible	VP Ancillary Services	Revised/Reviewed	12/15/2022~~10/23/2020~~

Use this document in conjunction with the Operation Manual for D-10 Hemoglobin Testing System and the D-10 Customer Training Manual.

INTENDED USE

The Bio-Rad D-10™ Hemoglobin A1C Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The measurement of the percent hemoglobin A1C is effective in monitoring long-term glucose control in individuals with diabetes mellitus, and measurement of the percent HbA2 and HbF are effective in long-term monitoring of β–thalassemias (i.e., hereditary hemolytic anemias characterized by decreased synthesis of one or more types of abnormal hemoglobin polypeptide chains).

CLINICAL SIGNIFICANCE

Diabetes mellitus is a condition characterized by hyperglycemia resulting from the body's inability to use blood glucose for energy. In Type 1 diabetes, the pancreas no longer makes insulin and therefore, blood glucose cannot enter the cells to be used for energy. In Type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly. The direct and indirect effects of hyperglycemia on the human vascular system are the major source of morbidity and mortality in both Type 1 and Type 2 diabetes. Therapy for diabetes requires the long-term maintenance of a blood glucose level as close as possible to a normal level, minimizing the risk of long-term vascular consequences. A single fasting blood measurement is an indication of the patient's immediate past condition (hours), but may not represent the true status of blood glucose regulation. The measurement of hemoglobin A1c (HbA1c) every two to three months has been accepted as a measure of glycemic control in the care and treatment of patients with diabetes mellitus. HbA1c, the glycohemoglobin of interest, is formed in two steps by the non-enzymatic glycation of HbA. The first step is the formation of an unstable aldimine (labile A1c, or pre-A1c), a reversible reaction between the carbonyl group of glucose and the N-terminal valine of the β-chain of hemoglobin. Labile A1c formation is directly proportional to the blood glucose concentration. During red blood cell circulation, some of the labile A1c is converted (Amadori rearrangement) to form a stable ketoamine, HbA1c. The D-10 Hemoglobin A1c Program is based on chromatographic separation of HbA1c on a cation exchange cartridge. Separation is optimized to minimize interferences from hemoglobin variants, labile A1c, and carbamylated hemoglobin.

PRINCIPLE

The D-10 Dual Program is based on chromatographic separation of the analytes by ion exchange high performance liquid chromatography (HPLC).The samples are automatically diluted on the D-10 and injected into the analytical cartridge. The D-10 delivers a programmed buffer gradient of increasing ionic strength to the cartridge, where the hemoglobins are separated based on their ionic interactions with the cartridge material. The separated hemoglobins then pass through the flow cell of the filter photometer, where changes in the absorbance at 415 nm are measured. The D-10 software

performs reduction of raw data collected from each analysis. Two-level calibration is used for quantitation of the HbA2/F/A1c values. A sample report and a chromatogram are generated for each sample. The A1C area is calculated using an exponentially modified Gaussian (EMG) algorithm that excludes the labile A1c and carbamylated peak areas from the A1c peak area.

SPECIMEN REQUIREMENT

Blood is collected in a lavender top tube (EDTA) and refrigerated at 2-8°C. Whole blood is stable 4 days at 2-8°C or 24 hours at room temperature (15 – 30° C). Lipemia up to a level of 5680 mg/dL of triglycerides does not interfere. Icterus up to a level of 20 mg/dL does not interfere. Hemolysis of the sample is not relevant, as whole blood is hemolyzed in the course of the analysis.

- Acceptable container sizes are 5 mL.
- Samples with less than 2.0 mL volume (or height less than 25 mm), or clotted samples, require pre-dilution before being placed on the D-10.
- Allow sample tubes to reach room temperature (15–30 °C) before performing the assay. No sample preparation is required. Mixing the tubes prior to loading is not necessary.

SPECIMEN COLLECTION AND HANDLING

- Specimen Type: Whole blood.
- Specimen Storage: Whole blood specimens may be stored up to 7 days at 2–8 °C or 3 days at room temperature (15–30 °C).
- Specimen Preparation:
- Allow sample tubes to reach room temperature (15–30 °C) before performing the assay. No sample preparation is required. Mixing has no impact on HbA1c value as long as the total area is in range.
- Load the sample tubes into the D-10 sample rack and place rack in the D-10. Ensure that the sample barcodes are facing towards the back of the instrument.
- Use special rack inserts for 12, 13, and 14 mm diameter tubes.
- Remove all inserts for 16 mm diameter tubes. Tubes with a height of 75 mm to 100 mm are acceptable for use.
- If the sample is in an abnormal size/type tube, or if there is less than 2.0 mL of sample in the tube, then the sample must be prediluted.
- Before pipetting, thoroughly mix the sample by gently inverting the tube.
- To predilute, pipet 1.5 mL of Wash/Diluent Solution into a labeled 1.5 mL vial, followed by 5 µL of the whole blood sample. Cap the sample vial and mix thoroughly. Use a sample vial adapter for 1.5 mL vials.

REAGENTS

The D-10 Dual Program Kit (Reorder Pack Cat. No. 220-0201) contains supplies sufficient for 200 analyses of Hb A2/F/A1c.

Elution Buffer 1	Two bottles containing 2000 mL of a Bis-Tris/Phosphate buffer, pH 6.0. Contains <0.05% sodium azide as a preservative.
Elution Buffer 2	One bottle containing 1000 mL of a Bis-Tris/Phosphate buffer, pH 6.7. Contains <0.05% sodium azide as a preservative.
Wash/Diluent Solution.	One bottle containing 1600 mL of deionized water with <0.05% sodium azide as a preservative.
Analytical Cartridge	One cation exchange cartridge
Floppy Diskette	With D-10 Hemoglobin A1c Program parameters.
Calibrator/Diluent Set	One set consisting of three vials of Calibrator Level 1. Three vials of Calibrator Level 2, and one bottle of Calibrator Diluent. The calibrator vials contain lyophilized human red blood cell hemolysate with gentamicin, tobramycin, and EDTA as preservatives. Reconstituted volume is 7 mL per vial. Calibrator Diluent contains 100 mL of deionized water with <0.05% sodium azide as a preservative.
Thermal Paper	1 roll

NOTE: The D-10 calculates buffer levels and waste level assuming test volumes of 200 or more tests per month and four or more samples per run. Low-test-volume users will run out of buffers and fill the external waste tank before the applicable warning messages are displayed. Visually check the buffer levels and waste tank level prior to each run.

CALIBRATION

Each new kit must be primed and calibrated once per kit. Primer and Calibrators are included in each kit. Calibrators – reconstitute with 7mL cold calibrator diluent. Stable 7 days @ 2-8C Primer - reconstitute with 1mL diH2O. Stable 1 day @ 2-8C

QUALITY CONTROL

Bio-Rad Lymphochek Diabetes Control Levels 1 & 2 must be run each day of use. Controls are prediluted 1:300 (5uL control to 1.5mL wash diluent) in a microvial. Microvials are placed in barcode labeled tube adapters

PREPARATION AND STORAGEOF REAGENTS

Refer to the insert included with the current lot of calibrators and controls for value assignment and ranges. When changing to a different lot of reagents and/or cartridge, the parameters from the matching floppy diskette must be installed to ensure optimum performance of the program.
To install or change Elution Buffers, Wash/Diluent Solution, and Analytical Cartridge, follow the procedures described in the D-10 Operation Manual, Section 4.2.

Elution Buffers and Wash/Diluent Solution

1. Allow the Elution Buffers and Wash/Diluent Solution to reach room temperature (15–30 °C) before performing the assay. Mix each bottle by gently inverting prior to installation.
2. The Elution Buffers and Wash/Diluent Solution will be stable until the expiration date when stored unopened at 15–30 °C. After opening the bottles, these reagents are stable for 8 weeks when stored at 15–30 °C.
3. With a new reorder pack, install one bottle of each reagent and follow the procedure for Installing a New Reorder Pack Lot in the Procedure section. After 200 injections, install a fresh bottle of Elution Buffer 1. Reset the volume in the LOT INFO/Buffer 1 screen after installing this reagent.

   NOTE: When using the optional D-10 Rack Loader, the two bottles of Elution Buffer 1 are

installed simultaneously. Manually resetting the volume is not required.

4. The Wash/Diluent Solution is interchangeable between Reorder Pack lots.

Whole Blood Primer

Use fresh aliquots of Whole Blood Primer when installing a new cartridge. The Whole Blood Primer will be stable until the expiration date when stored unopened at 2–8 °C.

1. Prepare the Whole Blood Primer by adding 1 mL of deionized water to the vial.
2. Allow to stand for 10–15 minutes at 15–30 °C.
3. Swirl gently to dissolve and ensure complete mixing.
4. Write the reconstitution date on the label. The reconstituted Whole Blood Primer is stable for 1 day when stored at 2–8 °C. The Whole Blood Primer is interchangeable between lots.

Hemoglobin A1C Calibrators

Reconstitute and store the HbA1c Calibrators as directed in the Calibrator/Diluent Set Insert.

QC REQUIREMENTS

In keeping with good laboratory practice, diabetic and non-diabetic control specimens should be included in the run once per 24 hours. A repeat run is indicated when expected control values are not obtained.

Liquichek Diabetes Control: Level 1, Level 2 and Level 3

Intended Use	Liquichek Diabetes control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid
Storage (Unopened)	10°C to -70°C until expiration date or 2 °C to 8°C for 6 months but should not be used past expiration date. *Note the refrigerated storage begins.*
Open Vial Claim	Once the control is opened, all analytes will be stable for 14 days
	when stored tightly capped at 2-8^{0}C. Once thawed, do not refreeze. Discard the remaining control material. This material is shipped under frozen conditions.
PROCEDURE This product should be treated the same as patient specimens and run in accordance with instructions accompanying the instrument, kit or reagent being used.	1. Allow the frozen control to stand at room temperature (18 to 25°C) for 30 minutes or until it is completely thawed. Before loading, gently swirl the vial several times to ensure homogeneity. 2. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

LIMITATIONS	1. This product should not be used past the expiration date. 2. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial. 3. This product is not intended for use as a standard. 4. This product contains gentamicin. Follow the instructions provided by manufacturer of the reagent and/or test system for samples containing gentamicin.

UPDATE KIT, CARTRIDGE, PRIME AND CALIBRATION

Frequency of update, prime, and calibration: Every installation of a new cartridge (200 injections). The software will prompt the user when 200 injections have been reached (analysis is not permitted past the allowed number of injections). Calibration must be performed after priming a new analytical cartridge and after installing a new lot of buffer. Thereafter, calibration should be repeated every 24 hours.

Calibration of A1C:

1. Place the following barcoded vial adapters in position1 through 4 of the sample rack: Cal1, Cal2, Low Control, High Control (can include patient sample).
2. Make sure barcodes are facing the back of the rack.
3. Pipette 1 ml of each sample type in the designated vial. Calibration do not require pre-calibration. Controls require 1:300

QC Preparation

1. Reconstitute and store the controls according to the manufacturer's package insert. Bio-Rad Lyphochek Diabetes Controls must be diluted 1:300 prior to analysis.
2. Pipet 1.5 mL of Wash/ Diluent Solution into a labeled 1.5 mL vial, followed by 5 µL of the reconstituted control. Cap each control vial and mix thoroughly.
3. Bio-Rad Liquichek Diabetes Controls must be diluted 1:200 prior to analysis. Pipet 1.0 mL of Wash/Diluent Solution into a labeled 1.5 mL vial, followed by 5 µL of the control. Cap each control vial and mix thoroughly.

PROCEDURE

1. From HMS, run CH3 pending list.
2. Remove specimens from the refrigerator.
3. Mix gently and allow to stand.
4. From the RUN tab, press START UP. Startup takes about 20 minutes.
5. When D10 is ready, it will display Standby on the bottom of the screen and will count down 30 minutes before it returns itself to Sleep mode.
6. Whole blood (EDTA) samples are used in their primary tubes with the caps left on. The D10 will read the barcodes. Pre-dilute samples less than 2mL d in a labeled adapter.
7. Edit sample ID after the rack is loaded
8. Load rack at the right side of the D10. Position barcodes facing the rear of the D10
9. Use the guides to autoload
10. Check the screen to be sure that the barcodes are correctly read.

11. Use the touch screen to highlight any specimens that need identification (specimens without barcodes), then press the Edit button and use the onscreen menu to enter specimen number or name.
12. Press RUN. Then you will need to tell it “yes” to start run.
13. When run is complete a button called Eject will appear. Use this to remove the rack. You can then load another rack or, if you are finished, just leave the D10 and it will put itself to Sleep. Do not press Shutdown!
14. Results are entered and verified manually using the CMAN worksheet.
15. Review Results Review results for 4 criteria on the printouts.
    1. Total Area count must be within 1.5 to 4.0 million.
    2. A1C and AO peaks must be present.
    3. Baseline must be flat and near the bottom.
    4. A1C peak is within linearity (3.8 – 18.5%).

EXPECTED RESULTS: Expected range = 4.4 – 6.4%

GUIDELINES FORTHE INTERPRETATION OF RESULTS

1. Observe the following guidelines to assure acceptable results:
2. The D-10 has passed calibration. For your reference, the slope and intercept acceptable ranges are provided in the D-10 Hemoglobin A1c Program Calibrator/Diluent Set Insert.
3. Total area of each analysis should range from 1.0 to 5.0 million µvolt•second. Results should not be reported if the area is outside this range.
4. The peaks are correctly identified. For your reference, the analyte retention time windows are provided in the D-10 Hemoglobin A1c Analytical Cartridge Insert.
5. Quality Control values are in range.
6. The reportable range for HbA1c was established based on data presented in Performance Characteristics, Linearity/Recovery. If the HbA1c result falls outside the reportable range, it should not be reported.

	Reportable Range
NGSP % HbA_{1c}	3.8–18.5
IFCC mmol/mmol HbA_{1c}	18–179

7. Any sample with >15% or >140 mmol/mmol HbA1c should be suspected of having a hemoglobin variant.13
8. Any sample with a combined area of 60% in the Variant, S, and C windows should be suspected of having a homozygous variant or a variant–β-thalassemia phenotype. The HbA1c result should not be reported for these samples.
9. P3 Peak Resolution
10. The P3 peak may split due to improved resolution. When this occurs, an "Unknown" peak will be listed in the peak table following the P3 peak (see Figure 4). The presence of this "Unknown" peak has no effect on the HbA1c quantitation.

LIMITATIONS OFTHE PROCEDURE

Sample Dilution

Normal total hemoglobin concentration corresponds to a total area of approximately 2.5 million µvolt•second. Low, medium, and high whole blood patient samples were diluted to achieve total areas from1.0 to 5.0 million µvolt•second. These samples were run on the D-10 Hemoglobin A1C Program to

confirm that the total area does not affect the result. The recommended total area range is from1.0 to 5.0 million µvolt•second.

If the sample area is outside of the expected range, manually pre-dilute the sample following the Specimen Preparation guidelines.

If the sample area is still outside of the expected range, the sample should be re-diluted to within the 1.0 to 5.0 million total area count range and rerun.

NOTE: For some high total area, high HbA1c samples (e.g., 15% or 140 mmol/L HbA1c with 5 M total area), the A1c peak may elute outside of the established retention time window. Predilute the sample to approximately 2.5 M total area and rerun.

Abnormal Red Cell Survival
Samples from patients with hemolytic anemias will exhibit decreased glycated hemoglobin values due to the shortened life span of the red cells. This effect will depend upon the severity of the anemia. Samples from patients with polycythemia or post-splenectomy may exhibit increased glycated hemoglobin values due to a somewhat longer life span of the red cells.15

Hemoglobin Variants
HbA1c values determined using the D-10 Hemoglobin A1c Program for HbS trait and HbC trait specimens showed no clinically significant difference from values determined by an NGSP certified boronate affinity method.
Other abnormal hemoglobin variants have not been evaluated on the D-10 Hemoglobin A1c Program. For the positive confirmation of any particular hemoglobin variant, alternative separation methods are required.

REFERENCE VALUES

Hemoglobin A1C Ranges
The following HbA1c ranges may be used for interpretation of results; however, factors such as duration of diabetes, adherence to therapy, and the age of the patient should also be considered in assessing the degree of blood glucose control. These values are for nonpregnant individuals. "Action Suggested" depends on individual patient circumstances.
Such actions may include enhanced diabetes self-management education, co-management with a diabetes team, referral to an endocrinologist, change in pharmacological therapy, initiation or increased self-monitoring of blood glucose, or contact that is more frequent with the patient.

Hemoglobin A_{1c} (%)	Degree of Glucose Control
> 8	Action Suggested†
< 7	Goal‡
< 6	Non-Diabetic Level

REFERENCES

Bio-Rad D10 Hemoglobin Testing System Operator Manual. Bio-Rad D10 Customer Training Guide.

WATSONVILLE COMMUNITY HOSPITAL

Policy Title	StatSpin Express 4 Horizontal Centrifuge	Policy #	CHEM2821
Responsible	Laboratory	Revised/Reviewed	1215/2022~~01/2021~~

I. PURPOSE

The StatSpin® Express 4 is a high-speed horizontal bench top centrifuge used to rapidly separate blood components in the original sample collection tubes. Do Not centrifuge substances with a density greater than 1.2 kg/dm3.

The horizontal rotor included with the centrifuge accepts up to 8 primary 16x100mm primary blood tubes with a maximum volume of 10 mL per tube. The operator selects a fixed spin time of 3, 5 or 10 minutes. The rotation speed is 5100 rpm for the 3 and 5 minute cycles, producing a centrifugal force of 4000 xg at a rotor radius of 13.8 cm. The 10 minute cycle generates 3100 xg at 4500 rpm. This setting provides lower g-forces for procedures which require a traditional spin.

II. POLICY

- **Required Cycle:** Troponin must be spun down using StatSpin Express 4 Horizontal Centrifuge at 5 minute cycle.
- **Specimen Type**: Plasma
- **Tube Type**: Specimen must be collected in a 3 ml Lithium Heparin BD Vacutainer tube (mint green).

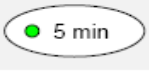
III. DEFINITIONS

N/A

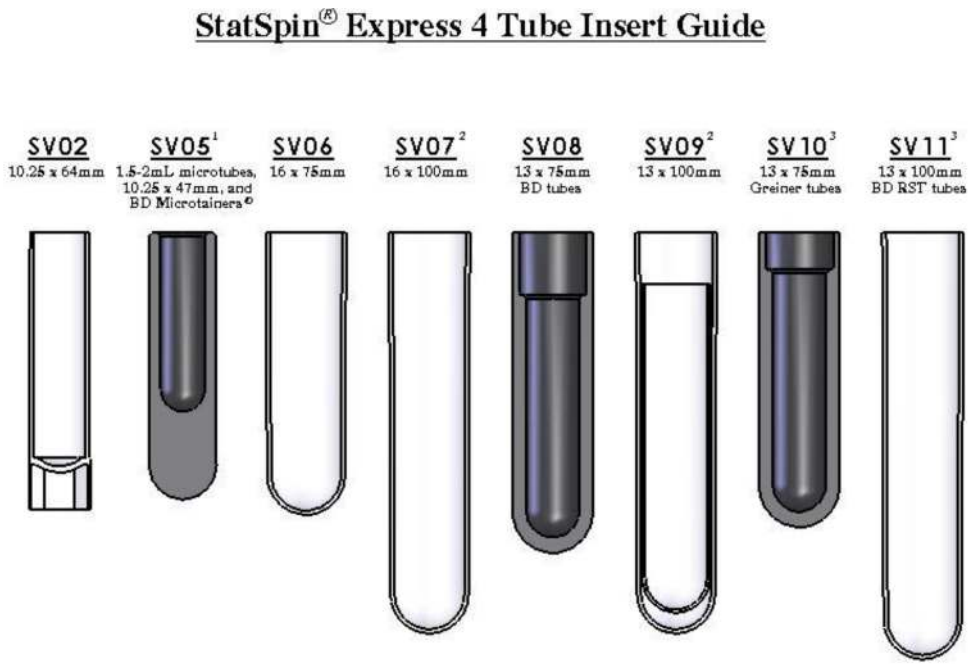
IV. INSTRUMENT OVERVIEW

A. The instrument is operated by using the different buttons; green arrow, red stop button, 3, 5, 10 min cycle button and error/service button.

Operator Controls

	Start	The *Start* button initiates the selected cycle.
	Stop/Open	The *Stop/Open* button interrupts the cycle and releases the cover when the rotor has stopped.
	3 Minute Cycle	The *3 min* button selects a cycle of three minutes at 5100 rpm.
	5 Minute Cycle	The *5 min* button selects a cycle of five minutes at 5100 rpm.
	10 Minute Cycle	The *10 min* button selects a cycle of ten minutes at 4500 rpm.
	Error/Service	The red indicator with an adjacent wrench symbol flashes to signal an error condition or remains continuously illuminated once the rotor reaches 50,000 cycles.

B. The tube must be inserted properly to achieve optimal result. Please see guide below.



IV. PROCEDURE

A. **Loading**

1. Ensure the appropriate tube inserts are installed.
2. The rotor must be properly balanced to ensure smooth operation. DO NOT spin a single tube.
3. Use the same size and style tubes in opposite positions. Balance liquid in tubes to within 0.5 mL.
4. Close and latch the centrifuge cover.
5. Select the spin time by pressing the appropriate cycle time button (5 min cycle).
6. Press *Start* button.

B. **Unloading**

1. Upon completion of the cycle, the rotor decelerates to a stop, a signal beep will sound, and the cover latch automatically releases.
2. Lift the cover and carefully remove the tubes.

C. Cycle Setting

The operator should select spin time settings to achieve optimum results for specific applications. The following are general guidelines:

Setting	Speed	RCF
3 min Produces high quality plasma/serum from whole blood for chemistry and cardiac testing.	5100 rpm	4000 xg
5 min Produces high quality plasma/serum from whole blood for chemistry and cardiac testing. Recommended for most Greiner gel tubes	5100 rpm	4000 xg
10 min Slower traditional spin. Centrifugal forces are decreased to provide a traditional spin.	4500 rpm	3100 xg

D. Cleaning

The StatSpin® Express 4 is equipped with a stainless steel bowl for easy cleaning. Clean the outside surfaces and switch overlay panel with a water-dampened cloth and mild detergent. Clean the inner surface or bowl with a mild detergent, and if necessary, a disinfectant, wiping surfaces with a **dampened** cloth using 70% alcohol or 10% bleach solution. Do not sterilize rotor. Cleaning must be done on daily basis.

V. TROUBLESHOOTING/ERROR MESSAGES

1) StatSpin® Express 4 error conditions are signaled by a flashing red *Error/Service* indicator on the control panel (See red arrow).

2) The cause of the error condition can be identified by the combination of green cycle time indicators that are also flashing. See Error Codes Table.

Error Codes Table

3 min	5 min	10 min	
●			**Failure to reach speed in 30 seconds.** *Confirm no obstruction in bowl area, contact customer service.*
	●		**Latch is not locked.** *Confirm cover is fully seated in closed position.*
●	●		**Rotor exceeded set speed.** *Remove and inspect rotor, reinstall.*
		●	**Cover is not closed.** *Confirm cover is fully seated in closed position.*
●		●	**Out of balance.** *Confirm tubes are balanced in rotor and centrifuge is on a level surface.*
	●	●	**Locked Rotor** *Contact customer service. Confirm no obstruction in bowl area*
●	●	●	**Shield is not installed.** *Confirm shield is installed and in the locked position.*
Continuously illuminated Error / Service indicator. ●			**Cycle Counter** *50,000 spins have been reached, please conduct periodic maintenance check (See Section 4).*

3) To clear the error condition, correct the problem and press the *Stop/Open* button.

VI. REFERENCE

Statspin Express 4 Operator's Manual, A Division of Iris International, Inc.

WATSONVILLE
COMMUNITY HOSPITAL

Policy/Procedure Title	Medical Staff Policy Regarding Peer Review, Ongoing Professional Practice Evaluation (OPPE) & (FPPE)	**Manual Location**	Medical Staff, Quality Management		
Policy/Procedure #	2842	**Effective**	9/12	**Page**	1 of 11
Department Generating Policy	Medical Staff , Quality Management	**Revised**	~~12/18~~01/17/2023		

I. SCOPE

Applies to all credentialed members of the Medical Staff and Allied Health Practitioners.

EXCEPTION:
No volume providers with medical staff membership and without clinical privileges per Joint Commission clarification are exempt from the Ongoing Professional Performance Evaluation and Focused Professional Practice Evaluation requirements contained within this document.

II. PURPOSE:

To assure that the Board of Trustees, through the activities of its medical staff, assesses the ongoing professional practice and competence of its medical staff, conducts professional practice evaluations, and uses the results of such assessments and evaluations to improve professional competence, practice, and the quality of patient care;

To define those circumstances in which an external review or focused review may be necessary

To address identified issues in an effective and consistent manner.

"Professional Practice Evaluation" is considered an element of the peer review process and the records and proceedings relating to this policy are confidential and privileged to the fullest extent permitted by applicable law.

III. DEFINITIONS

Peer:
For purposes of this policy, the term "Peer" refers to any practitioner who possesses the same or similar knowledge and training as the practitioner whose care is the subject of review.

IndividualCaseReview:
The process outlined for peer review of a particular case identified with a potential quality of care issue.

OngoingProfessionalPracticeEvaluation:

The ongoing process of data collection for the purpose of assessing a practitioner's clinical competence and professional behavior. Information gathered during this process is factored into decisions to maintain, revise, or revoke an existing privilege(s) prior to or at the time of the two-year membership and privilege renewal cycle.

FocusedProfessionalPracticeEvaluation:

The time-limited evaluation of practitioner competence in performing a specific privilege. The process is consistently implemented as a means to verify clinical competence for all initially requested privileges, for a newly requested privilege, and whenever a question arises regarding a practitioner's ability to provide safe, high-quality patient care. FPPE is not considered an investigation or corrective action as defined in the Medical Staff Bylaws and is not subject to the Bylaws provisions related to the corrective action process.

FPPE affects only the privileges for which a relevant concern has been raised and related privileges for which the same concern would apply. Other existing privileges in good standing should not be affected by the decision to initiate FPPE.

PeerReview

Peer Review is the process by which a practitioner, or committee of practitioners, examines the work of a peer and determines whether the practitioner under review has met accepted standards of care in rendering medical services. The professional or personal conduct of a physician or other healthcare professional may also be investigated. Individual Case Review, Ongoing Professional Practice Evaluation, and Focused Professional Practice Evaluation are components of peer review.

PractitionerProctoring:
Please Refer to Proctoring Policy (#0158)

FocusedProfessionalPracticeEvaluation(FPPE)

A. Initiation of FPPE

FPPE will be initiated in the following instances:

- Upon initial appointment;
- When a new privilege is requested by an existing practitioner;
- When a question arises through the OPPE process, individual case review, or other peer review process regarding a currently privileged practitioner's ability to provide safe, high-quality patient care. For example, when a trigger is exceeded and preliminary review indicates a need for further evaluation.

A recommendation of FPPE may be made by:

- The Credentials Committee;
- A Department of the Medical Staff;
- The Chief of the Department;
- A special committee of the medical staff;
- The MEC

The FPPE monitoring plan for a new practitioner, or newly requested privilege(s) will be specific to the requested privileges or group of privileges as defined in the Medical Staff Proctoring policy.

FPPE is not considered an investigation as defined in the Medical Staff Bylaws and is not subject to the bylaws provisions related to investigations. If FPPE results in an action plan to perform an investigation, the process identified in the Medical Staff Bylaws would be followed.

B. Timeframe for Collection and Reporting

The period of FPPE must be time-limited. Time-limited may be defined by;

A specific period of time;

A specific volume (number of procedures/admissions)

The medical staff may take into account the practitioner's previous experience in determining the approach, extent, and time frame of FPPE needed to confirm current competence. The practitioner's experience may be individualized based upon one of the following experience/training examples:

1. Recent graduate from a training program at another facility, where the requested privileges were part of the training program (competence data is not available)
2. A practitioner with regular experience exercising the requested privilege of fewer than two to five years on another medical staff

FPPE shall begin with the applicant's first admission(s) or performance of the newly requested privilege. FPPE should optimally be completed within three months, or a suitable period based upon volume. The period of FPPE may be extended as necessary at the discretion of the medical staff but may not extend beyond the first biennial reappointment.

C. Methods for Conducting FPPE/Communication to the Practitioner

FPPE may be accomplished by:

1. Chart reviews, both concurrent and/or retrospective
2. Simulation
3. Discussion with the involved practitioner and/or other individuals involved in the care of the practitioner's patients
4. "Non-Mandatory" Direct observation/proctoring, i.e., observation/proctoring of a nature that does not restrict the physician's privileges or right to practice in the hospital, including the right to proceed with procedures or surgeries. Non-Mandatory observation/proctoring preserves the physician's right to proceed with a procedure or surgery regardless of the presence of an observer/proctor. Any requirement to the contrary is reserved solely for decision of the Medical Executive Committee, may implicate reports to the Board and Data Bank, and may require the grant of hearing rights under the Medical Staff Bylaws.
5. For dependent AHP's, FPPE methods may include review or proctoring by the sponsoring physician.
6. Internal or external peer review.

The terms of all FPPE shall be communicated in writing to the affected practitioner, including the following:

- The cause for the focused monitoring
- The anticipated duration
- The specific mechanism by which monitoring will occur (i.e. chart reviews, proctoring, peer observation, etc.)

D. Performance Monitoring Criteria and Triggers

Monitoring criteria, including specific performance elements to be monitored, as well as thresholds or triggers, are developed and approved by the medical staff or medical staff department/committee. The triggers are defined as potentially unacceptable levels of performance. Triggers to consider include, but are not limited to:

- A single egregious case or evidence of a practice trend
- Exceeding the predetermined thresholds established for OPPE
- Patient/staff complaints
- Non-compliance with Medical Staff Bylaws, Rules and Regulations
- Elevated infection, mortality and/or complication rates
- Failure to follow approved clinical practice guidelines
- Unprofessional behavior or disruptive conduct

If the results for a practitioner exceed thresholds established by the Medical Staff, outliers may be forwarded for peer review after initial screening by the Quality Management Department.

Attachment B Performance Measures & Triggers

E. Conclusion of FPPE

At the conclusion of the initial FPPE, findings will be reviewed by the Medical Executive Committee or responsible Department, for decision and recommendation. Decisions may include moving forward with OPPE, extending the period of FPPE, development of a performance improvement plan, or recommending to limit or suspend the privilege. Such recommendations are reported to and approved by the Medical Executive Committee and Board of Trustees. For recommendations resulting in restriction, suspension, revocation of specific privileges or other limitation on privileges, the processes pursuant to the Medical Staff Bylaws Appendix A (Fair Hearing Plan) will apply.

Each practitioner will be notified of their performance and outcome(s) following FPPE. A letter is forwarded to the Medical Staff member including, but not limited to, the following:

- Findings and outcome of FPPE
- Specific actions, if any, that need to be taken by the Practitioner to address any quality concerns and the method for follow-up to ensure that the concerns have been addressed; and
- If the focused review is complete or will continue (duration will be specific if the focused review will continue)
- The period of initial FPPE is completed and the practitioner will move into OPPE
- The period of FPPE for a specific privilege is completed and the practitioner will continue with OPPE

At the end of the period of focused evaluation, in the event that the practitioner's activity/volume has not been sufficient to meet the requirements of FPPE:

- The practitioner may voluntarily resign the relevant privilege(s), or
- The practitioner may submit a written request for an extension of the period of focused evaluation, or
- If the practitioner has sufficient volume of the privileges in question at another local facility, external peer references specific to the privilege/procedure will be obtained.
- FPPE may be extended at the discretion of the responsible medical staff department or committee.

The practitioner is not entitled to a hearing or other procedural rights for any privilege that is voluntarily relinquished.

Results of FPPE are maintained in the Practitioner's Confidential Quality File.

F. Performance Improvement Plan

If FPPE outcomes identify the need for an improvement plan, the plan will be drafted by the responsible medical staff department, committee or chair. The written improvement plan and supporting FPPE outcomes should be presented to the Medical Executive Committee for approval. The involved Practitioner should also be offered the opportunity to address the Committee and respond to the findings before the improvement plan is finalized and implemented.

Methods identified to resolve performance issues shall be clearly defined. Examples of improvement methods may include:

- Necessary education
- Proctoring (but only as described under Section C.) and/or mentoring
- Counseling
- Practitioner Assistance Program
- Suspension or revocation of privilege, subject to the provisions of the Bylaws.

Following approval by the Medical Executive Committee (MEC), the Department or Committee Chair, or Chief of Staff will meet with the Practitioner to communicate the improvement plan. If the Practitioner agrees with the plan, the written document should be signed by the Practitioner and forwarded to the Quality Department. If the Practitioner does not agree with the plan and/or refuses to implement the improvement plan, the outcome will be reported to the responsible department chief and/or Medical Executive Committee for resolution.

ONGOING PROFESSIONAL PRACTICE EVALUATION

A. Timeframe for Collection and Reporting

OPPE will be initiated and reported on all providers with clinical privileges. Results of OPPE will be reported for review and/or action six months if possible, and in no event less frequently than every nine months.

B. Indicators for Review

1. The type of data to be collected and related thresholds, or triggers, is determined by individual medical staff committees/departments and approved by the Medical Staff. Indicators may change as deemed appropriate by the department and/or medical staff and should be reviewed and approved on an annual basis. Data collected should not be limited to negative/outlier trending data. Good performance data should also be considered.

    a. Each Medical Staff department will select three to five *specialty-specific* indicators based upon their clinical service. These indicators may be evidence-based, such as post-op infection rate, etc.
    b. The Medical Staff will select *general* indicators that apply to all credentialed practitioners.
    c. The Medical Staff may consider using the six areas of "General Competencies" developed by the Accreditation Council for Graduate Medical Education (ACGME). These include:
        i. Patient care
        ii. Medical/clinical knowledge
        iii. Practice-based learning and improvement
        iv. Interpersonal and communication skills
        v. Professionalism
        vi. Systems-based practice

2. Thresholds/triggers for performance must be defined for the selected indicators. Triggers are defined as unacceptable levels of performance within the established defined criteria and are used to identify those performance outcomes that could trigger FPPE. Triggers to consider include, but are not limited to:
    Defined number of events occurring
    Defined number of individual peer reviews with adverse determinations
    Elevated infection, mortality, and/or complication rates
    Sentinel events
    Small number of admissions/procedures over an extended period of time
    Increasing lengths of stay in comparison to peers
    Increasing number of returns to surgery
    Frequent unanticipated readmission for the same issue
    Patterns of unnecessary diagnostic testing/treatments
    Failure to follow approved clinical practice guideline

3. Two level 4 judgments within a rolling 24 month period
4. Any combination of four level 3 and 4 judgments within a rolling 24 month period
5. 3 incidents of significant disruptive behavior incidents (as judged by MEC) within a rolling 12 month period

C. Oversight and Reporting

The organized Medical Staff delegates the collection of the selected performance indicators to the appropriate hospital department. The overall process, data compilation and reporting is coordinated by the Quality Management Department.

The review of performance data and any recommendation(s) for action, if necessary, may be the responsibility of one of the following:

The Medical Executive Committee;
The specific Medical Staff Department;
The Chief of the Department;
The Medical and Surgical Quality Review Committees

D. Results and Reporting of Data Analysis

Data are analyzed and reported to determine whether to continue, limit, or revoke any existing privilege(s). The results of the individualized practitioner report are referenced in the MEC meeting minutes, maintained in the quality file and incorporated into the two-year reappointment process.

The outcome of the evaluation must be documented and maintained in the practitioner quality file.

During the course of OPPE, FPPE may be triggered by the following special circumstances:

A single egregious case or evidence of a practice trend
Exceeding the predetermined thresholds established for OPPE
Patient/staff complaints
Non-compliance with Medical Staff Bylaws, Rules and Regulations
Elevated infection, mortality and/or complication rates
Failure to follow approved clinical practice guidelines
Unprofessional behavior or disruptive conduct

If unprofessional behavior or disruptive conduct is identified as a possible concern, the Disruptive Practitioner Policy will be initiated as a component of the OPPE.

At the completion of the review period, the results of OPPE (the practitioner profile report) will be communicated to the individual practitioner. The original report will be maintained in the practitioner quality file.

RESPONSIBILITIES OF THE QUALITY MANAGEMENT DEPARTMENT:

1. The Quality Management Department will be responsible for compiling and reporting results of FPPE and OPPE to the Medical Staff Committee(s) every six months in no event less frequently than every nine months. A practitioner-specific profile will be utilized.

2. In order to facilitate FPPE for Allied Health Professionals, and/or those practitioners requesting a new privilege, the practitioner must notify the Quality Management Department of the first scheduled procedure or encounter. The practitioner must also provide the Quality Management Department with a patient listing or log until the specified patient volume or FPPE requirement is met.

3. The OPPE practitioner-specific profile that illustrates performance over the two-year reappointment cycle will be utilized at the time of reappointment.

4 The Quality Management Department will be responsible for working with each Medical Staff Committee on an annual basis to review the continued relevance of the selected indicators and triggers.

Individual Case Review Process

Cases identified with potential quality of care issues are referred to either the Medical Quality Review Committee or Surgical Quality Review Committee for review. The Quality Management Department is responsible for coordinating the Peer Review Process.

Cases may be identified through OPPE, FPPE, case management, risk management, audits, sentinel events, clinician referrals, allegations of suspected substance abuse or disruptive behavior and other sources. All cases should be initially screened by the Quality Management department utilizing medical staff approved screening criteria, prior to forwarding for physician review. If there are no potential quality of care issues identified following the quality management screening, the case is closed, the findings are documented and trending is performed in the Quality Department.

If potential quality of care issues are identified through Quality Management screening, the following process for peer review shall be implemented:

A. ReviewerSelection&Duties

Reviews are completed by the designated Medical Staff Quality Review Committee.

The Committee Chair shall determine the individual physician(s) to perform the initial review and shall designate a deadline within which the individual physician reviewers shall complete the review which shall not be greater than 60-days and at least 2 weeks prior to the next committee meeting. This will allow time for the involved Practitioner to respond prior to the meeting (see below Communication to Involved Practitioner).

The individual physician reviewer(s) shall perform the initial review, complete the Peer Review Form, including initial grade (see Review Form Summary below). The reviewer will report written findings and recommendations to the Committee at its next regularly scheduled meeting following the completion of the review period.

The designated reviewer may not review a case where he/she participated in the care.

B. ReviewerDisqualification&Replacement

If a reviewer does not feel he/she can adequately review a medical record due to a conflict of interest or believes he/she is not qualified to address a certain issue, the reviewer may discuss the issue with the Chairperson of the Committee, Department Chief or Chief of Staff. If the Chair concurs, the Chair shall reassign the record(s) to another reviewer. If a member has reviewed a record that needs to be presented but is unable to attend the meeting, the member shall report to the Chair so that the presentation may be reassigned to another Committee member or presented by the Chairperson. If the chairperson is the practitioner subject to review, the record review will be assigned to another Active Staff member by the Chief of Staff. Should the hospital have only one practitioner in a particular specialty, or the pool of eligible reviewers is otherwise conflicted or unable to serve, the MEC or the Board of Trustees may request external peer review by a practitioner who is Board certified within the same specialty.

C. Communication to Involved Practitioner

Any Practitioner who is the subject of a review receiving an assigned peer review score of 3 or greater, shall be notified in writing at least two weeks prior to the medical staff meeting where the outcome of review is reported. Communication shall include the case medical record number, admission/discharge date, reason and outcome of the review. Comments and/or opinions made by the reviewer may be included; however, the identity of the reviewer should be redacted.

The involved Practitioner is provided the opportunity to respond to the results of the review in writing in advance of the meeting where the outcome is reported. At the request of the Department Chief, or Chief of Staff, the Practitioner may be invited to attend the meeting to discuss the case.

D. Circumstances Requiring External Peer Review

If no practitioner on staff is qualified to conduct a review, the MEC, Chief of Staff, Department Chair or the Board of Trustees may request external peer review by a practitioner who is Board certified within the same specialty. External Peer Review may be necessary, but not limited to, the following circumstances:

The pool of eligible reviewers is unable to serve
There is no qualified practitioner on staff to conduct the review
Litigation risk
The facility has only a single practitioner in a particular specialty and no other practitioner has similar background, training or experience.

No practitioner may require the Hospital to obtain external peer review if it is not deemed necessary by the Chief of Staff, Executive Committee or Board of Trustees.

Where the body conducting the peer review seeks external or outside peer review by a qualified practitioner within the same specialty or discipline as the practitioner under review, it shall appoint such external or outside reviewer to be a member of the peer review committee, without vote. Any report generated by such external or outside reviewer shall be considered to be a report of the peer review committee and shall be utilized for the committee's purposes. Likewise, where the peer review committee in its discretion affords the practitioner under review the opportunity to respond to the report of an external or outside reviewer, the practitioner shall attend a peer review committee meeting to discuss such response, and any information submitted by the practitioner under review in response to such report shall be considered to have been acquired in connection with or in the course of the peer review committee proceeding. An external or outside reviewer who is appointed to the peer review committee shall attend peer review committee meetings personally or telephonically, as is appropriate under the circumstances, for the purpose of deliberations related to any report by such external or outside reviewer. All information pertaining to any external or outside review by a qualified practitioner who is appointed to the peer review committee shall be protected to the fullest extent permitted by state law. For purposes of this paragraph, "peer review committee" shall include, without limitation, any medical review committee, departmental peer review committee, and the Medical Executive Committee.[1]

E. ReviewFormSummary

Reviewing practitioners must complete the Peer Review Form, Attachment One, clearly and concisely. The reviewing practitioner must sign his/her name on the review form which shall grade the care and outcome based on the following schedule:

1 = Treatment appropriate, outcome good, and any patient impact was minimal
2 = Treatment appropriate but patient sustained significant adverse outcome
3 = Treatment inappropriate but adverse impact on patient was minimal
4 = Treatment inappropriate and patient sustained a significant adverse outcome

DOCUMENTATIONOFPEERREVIEWACTIVITIES:

Reports of OPPE and FPPE and individual case review findings and recommendations shall be presented to the MEC. The MEC may adopt the recommendations of the Medical Staff Quality Review Committees and/or make further recommendations, including recommendation for further investigation and/or Corrective Action in accord with the Medical Staff Bylaws.

~~All recommendations of the MEC other than for further investigation or Corrective Action shall be delivered to the Board. The Board shall make a final determination concerning any actions warranted based on the findings and recommendations of the MEC.~~

Results of OPPE, FPPE and Peer Review outcomes shall be documented and maintained in the practitioner's quality file and referenced at reappointment.

~~**PractitionerReviewofConfidentialQualityFile**~~

~~A practitioner may review his quality file by making an appointment with the Director of Quality Management and Regulatory Compliance (QMRC)/Chief Quality Officer, and the Chief of Staff. No copies of the quality file may be made, nor may the practitioner remove any portion of the quality file from the Hospital. In the discretion of the CEO, in consultation with the Chief of Staff, personal information, such as the identity of external or internal peer reviewers, or the identity of patients or employees reporting quality issues, may be redacted before the practitioner may review the file.~~

IV. CONFIDENTIALITY OF REVIEW

All proceedings conducted as the result of this policy are subject to the California Evidence Code Section 1157 and The Health Care Quality Improvement Act of 1986 (HCQIA), 42 USC §11101.

Reviewed:	**1st**	**2nd**	**3rd**	**4th**	**5th**
Date:	4/15/14	9/20/16			
By:	D Salvi	MEC			
Revised	**1st**	**2nd**	**3rd**	**4th**	**5th**
Date:					
By:					

WORKSHEET

MEDICAL STAFF BUSINESS NOT TO BE INCLUDED IN PATIENT CHART

MQRC SQRC B&T

Physician #	Account #	Medical Record #	*INPATIENT* Admission Date	Discharge Date	Outpt./ER Date	Review Date

Referral Source:

□ QRC-specific process audits or clinical practice guideline audits. □ QRC-specific clinical indicators or outcome measurements.
□ Referrals from external agencies related to practitioner-specific issues. □ Sentinel events dealing with practitioner-specific issues.
□ Specific patient complaints dealing with clinical and/or practitioner specific issues. □ Hospital-wide generic indicators.
□ New legal cases identified by the organization, which may relate to physician performance. □ Staff concerns.
□ Referrals from other medical staff or organizational committees or team related to practitioner specific issues. □ Event reports.

Case Summary: _____

Key Questions for Reviewer: 1) _____
2) _____
3) _____

Reviewer Findings/Conclusions: _____

Case Review Scoring	
RN	□ Case reviewed by a RN outside of committee with no identified opportunity for improvement. □ Case referred to physician for review. RN Signature: _____
Care by the Physician	□ Treatment was appropriate and medically necessary. □ Treatment was not appropriate, either all or in part. *(See Practitioner Care Issues)* □ Treatment was not medically necessary. *(See Practitioner Care Issues)* □ Treatment was controversial, unproven, experimental or investigational. □ Treatment was not timely or not performed in the proper sequence. *(See Practitioner Care Issues)* □ Response time and/or ongoing assessment were not adequate. *(See Practitioner Care Issues)*
Practitioner care Issues: (*Check all that apply*)	□ Clinical Judgment/Decision-Making □ Communication/Responsiveness □ Diagnosis □ Follow-up/Follow-through □ Knowledge □ Planning □ Policy Compliance □ Supervision (House Physician or AHP) □ Technique/Skills □ Other: _____
Contributing Causes	□ Judgment of the physician. □ Contributing cause not identified □ Hospital systems/process issues. □ Failure by physician to comply with hospital/Medical Staff bylaws, Rules and Regulations. □ Issues identified with providers of care other than the physician under review. □ Inadequate documentation/not timely and/or poor interdisciplinary communication.
	□ Case reviewed by a physician outside of committee with no identified opportunity for improvement. □ Refer to QRC for Physician Concern or _____ □ Refer to QCC for Process Problem Reviewer Signature

ADDITIONAL COMMENTS MAY BE WRITTEN ON THE BACK OF THIS FORM.

Committee Review	Is physician/provider response needed? □ Yes □ No (Care Appropriate, no issues or concerns) If yes, letter sent □ Yes □ No Date 1: _____ Date 2: _____
Practitioner Response	□ Letter received and discussed □ No letter received
Committee Score	□ 1 – Treatment appropriate, outcome good and any □ 2 – Treatment appropriate, but in spite of that the patient sustained a significant adverse outcome. □ 3 – Treatment inappropriate, but the adverse impa □ 4 – Treatment inappropriate and the patient sustained a significant adverse outcome.

Additional Committee Recommendations: _____

_____

_____

_____

DISPOSITION

QRC Act

□ Refer to _____ □ External Peer Review

□ Informational Letter to _____ □ Track and Trend □ Case Closed

Chairperson Signature _____ Date _____

Privileged and confidential per CA business and professions Code 1157.

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Information

Title: Update by Chief Executive Officer (CEO)

Recommendation: Receive and file update from Steven Salyer, CEO

Contact: Steven Salyer, CEO

Analysis

Each board meeting the CEO provides the board and the public an oral update on various matters.

Financial Impact: None

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Discussion

Title: Association of California Healthcare Districts (ACHD)

Recommendation: Receive and discuss ACHD presentation given by Cathy Martin, CEO and Sarah Bridge, Senior Legislative Advocate.

Contact: Steven Salyer, Chief Executive Officer

Background

The Association of California Healthcare Districts (ACHD) represents Healthcare Districts throughout California. ACHD works with numerous state and local entities to promote the profound role Healthcare Districts play in responding to the specialized health needs of tens of millions of Californians while also having direct accountability to the communities that Districts serve.

Financial Impact: None for presentation

Attachment A: ACHD PowerPoint presentation

Attachment A

ACHD Presentation to Pajaro Valley Healthcare District

FEBRUARY 2023

Cathy Martin, CEO
Sarah Bridge, Senior Legislative Advocate

ACHD

ACHD Staff

Cathy Martin,
CEO

Sarah Bridge
Sr. Leg. Advocate

Michelle Rouse,
Member Services
and Facilities
Specialist

Latifah Alexander
Govt. Affairs
Coordinator

Mission

The Association of California Healthcare Districts (ACHD) serves the diverse needs of California Healthcare Districts through advocacy, member services and education.

Vision

To be the leading advocate for the shared interests of California Healthcare Districts through its work with local and statewide government and through its education and support of its membership.

Role of ACHD

The Association of California Healthcare Districts (ACHD) represents Healthcare Districts throughout the state's urban, suburban and rural areas. California is home to 76 Healthcare Districts that play a profound role in responding to the specialized health needs of local communities by providing access to essential health services to tens of millions of Californians while also having direct accountability to the communities that Districts serve. In many areas, Healthcare Districts are the sole source of health, medical and well-being services in their communities.

Membership

Alta
Antelope Valley
Beach Cities
Bear Valley
BETA
Bloss Memorial
Camarillo
Chowchilla
City of Alameda
Cloverdale
Del Puerto
Desert Healthcare
Eden Township
El Camino Health
Fallbrook
Grossmont
Heffernan
John C. Fremont
Last Frontier
Marin
Mark Twain
Mayers Memorial
Morongo Basin
Mountain Communities
Northern Inyo
Palomar
Peninsula
Petaluma
Pioneers
Plumas
Redbud
San Benito
Sierra Kings
Seneca
Sequoia
Soledad
Southern Humboldt
Tahoe Forest
Tulare Local Healthcare District
West Side Community (Newman)
West Side Health (Taft)

ACHD

Membership Benefits

- Advocacy for improved legislation, statewide policies and efficient regulations
- Access to educational training tailored to healthcare districts, including the monthly Webinar Education Series
- Exclusive email campaigns regarding the most relevant news
- Certified Healthcare District Program
- Board self-assessment
- CEO evaluation
- Governance Toolkit and support
- CEO Roundtable and networking opportunities
- Discount on Public Records Request Services from Best Best and Krieger

ACHD

Thank you to our ACHD Committee Members

- Education Committee
- Advocacy Committee
- Governance Committee
- Finance Committee
- Executive Committee

Current Legislative Issues Facing Healthcare Districts

Top Legislative Issues

- Seismic mandate compliance
- Ban on the corporate practice of medicine

District Level Challenges

- Finances in jeopardy, heightened by the pandemic
- Workforce shortages
- Addressing behavioral and mental health challenges

Questions

Cathy Martin
Cathy.martin@achd.org

Sarah Bridge
Sarah.bridge@achd.org

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
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
Each board meeting the CFO provides the board and the public an update on Financial Performance.

Financial Impact: See attached report.

Attachment A: Financial Performance Report (To be Delivered)

PAJARO VALLEY HEALTH CARE DISTRICT
HOSPITAL CORPORATION

Back

Board Report

Meeting Date: February 22, 2022
Report Type: Discussion

Title: Medical Committees Reports Report February 2023

Recommendation: Pass a **Motion** approving the Medical Executive Committee (MEC) Report, the Credentials Report and the Interdisciplinary Practice Credentials Report of February 2023.

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

Analysis
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.

Attachment A: Reports

WATSONVILLE COMMUNITY HOSPITAL

Medical Executive Committee Summary – February 21, 2023
ITEMS FOR BOARD APPROVAL

Credentials Committee

INITIAL APPOINTMENTS: (10)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Amin, Darshana, DO	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Chen, Ricky, MD	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Li, Sui, MD	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Liao, Yu-Hsuan, MD	Teleneurology Provisional y	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Novick, Andrew, DO	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Richardson, Colby, MD	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Stabley, Jason, DO	Teleneurology Provisional	Medicine	Teleneurology Neurology	02/23/2023 – 01/31/2025
Bui, Bao-Thuong, MD	GYN Surgery Provisional	Surgery	GYN Surgery Robotic GYN Surgery	02/23/2023 – 01/31/2025
Dogan, Ozge, MD	Pediatrics Provisional	Pediatrics	Pediatric Medicine	02/23/2023 – 01/31/2025
Mungal, Myrna, MD	Pediatrics Provisional	Pediatrics	Pediatric Medicine	02/23/2023 – 01/31/2025

REAPPOINTMENTS: (6)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Ferguson, Ian, DO	Emergency Medicine / Active	Emergency Medicine	Emergency Medicine Sedation	03/01/2023-02/28/2025
Hensel, Tyler, MD	Family Medicine Hospitalist / Active	Medicine	Family Medicine Critical Care, Non-Intensivist	03/01/2023-02/28/2025
Lane, Alexis, MD	Otolaryngology / Courtesy	Surgery	Otolaryngology Sedation	03/01/2023-02/28/2025
Nagamine, Janet, MD	Hospice & Palliative Care / Active	Medicine	Hospice & Palliative Care	03/01/2023-02/28/2025
Schmetz, Mark, MD	Radiology / Active	Medicine	Radiology	03/01/2023-02/28/2025
Segnitz, Lisa, MD	Hospice & Palliative Care / Refer and Follow	Medicine	Refer and Follow	02/25/2023-01/31/2025

MODIFICATION / ADDITION OF PRIVILEGES:

NAME	SPECIALTY	Privileges
None		

STAFF STATUS MODIFICATIONS:

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Aurora, Princy, MD	Neurology / Medicine	Recommend Honorary Staff Status; physician on staff since 11/1999 and retired 01/01/2023

TEMPORARY PRIVILEGES:

NAME	SPECIALTY / DEPARTMENT	DATES
Ahn, Johan, MD	Diagnostic Radiology / Medicine	01/30/2023 – 02/03/2023; 02/27/2023 – 03/03/2023
Dogan, Ozge, MD	Pediatric Hospitalist / Pediatrics	02/1/2023; 02/03/2023 – 02/28/2023
Dutaret, Claudine, MD	Teleneurology / Medicine	02/1/2023 – 02/07/2023
Guzman, Jose L., MD	Anesthesiology / Surgery	01/27/2023 – 02/13/2023 02/16/2023 – 03/31/2023
Phan, An, MD	Anesthesiology / Surgery	01/27/2023 – 02/28/2023

INTERDISCIPLINARY PRACTICE COMMITTEE

Initial Appointment: (1)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Zimmer, Barbara, CRNA	Nurse Anesthetist / Allied Health Professional	Anesthesia	Nurse Anesthetist	02/23/2023 - 01/31/2025

REAPPOINTMENT: (3)

APPLICANT	SPECIALTY / STATUS	DEPT	PRIVILEGES	Effective Date
Davis, Brooke, PA-C	Physician Assistant / Allied Health Professional	Surgery	Orthopedic Surgery Physician Assistant	03/01/2023-02/28/2025
Panattoni, Stephen, PA-C	Physician Assistant / Allied Health Professional	Surgery	Orthopedic Surgery Physician Assistant	03/01/2023-02/28/2025
Staley, Jamie, PA-C	Physician Assistant / Allied Health Professional	Surgery	Orthopedic Surgery Physician Assistant	03/01/2023-02/28/2025

STAFF STATUS MODIFICATIONS: (1)

NAME	SPECIALTY / DEPARTMENT	RECOMMENDATION
Reiland, Kimberly, PA-C	Physician Assistant / Surgery	Resignation; Effective 01/04/2023

MEDICAL EXECUTIVE COMMITTEE, February 21, 2023, ACTION ITEMS FOR APPROVAL

1. Credentialing Actions:

1.1 Credentials Report: February 2023
1.2 Interdisciplinary Practice Credentials Report: February 2023