KAISER PERMANENTE

*Kaiser Permanente Medical Center, San Francisco*
*Northern California Region*
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# Work Instruction

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| **Title:** | **TC Quality Control-Weekly Monthly Quarterly Annually** | **WI Number** SFOWI-0032<br>**Revision:** 21 |
| **Department:**<br>Immunohematology<br>**Area:**<br>2425 Geary Blvd SFO Hospital Lab | ***Document is in the Final Approval Process. 2 - approvals are required*** | |
| **Type of Document:**<br>Work Instruction | | **Review Period -** 340 **Days** |

## PURPOSE

To ensure proper operation, specific guidelines must be adhered to on a daily, weekly, monthly and annually basis. Constant monitoring is imperative to detect any problems, equipment malfunctions or deficiencies so corrective action can be immediately taken. All instruments must be maintained and monitored on a timely basis to ensure accurate testing.

## QUALITY CONTROL

A. Complete Blood Bank Quality Control Checklist form.
B. Supervisor reviews logs and reports monthly.

## PROCEDURE

**NOTE: Please refer to each equipment's specific SOPs for detailed maintenance instructions. Refer to Transfusion Service QC/Maintenance/Validation Schedule for the months designated to perform tasks.**

### A. Weekly

1. Perform **Check Point Alert Device activation** check on **Friday**.
2. **Change temperature charts** of refrigerators, freezers and platelet incubator on **Monday**.
   a. Make sure that the pen is recording the correct temperature on the correct date and time.
   b. Document corrective action on the chart if temperature is out of range.
3. **Platelet Incubator agitator motion alarm** check on **Monday**.
4. Perform weekly maintenance on **ProVue**.
5. Perform weekly maintenance on **Cell washers**.
6. Perform weekly maintenance on **Centrifuges**.
7. Perform weekly maintenance on HELMER **DH8** Plasma Thawer.
8. Perform weekly backup of Access database for **Blood Bank Specimen Problem and Product Wastage**.

**B. Monthly and Bi-monthly**

1. **Computer data integrity** check.
2. **ProVue** monthly maintenance including backup of data files.
3. Check **noncellular & cellular blood product physical inventory alternatively every two months.**
    a. Go to Inventory Search of RILIS Millennium.
    b. Select RBC (see schedule for designated months) or plasma products (see schedule for designated months), specifying ABO and Rh, 365 days to expire and All active status.
    c. Deselect Autologous, Shipment in Process, Shipped, Transfused, Destroyed, Directed, Dispensed, Disposed and Drawn.
    d. Click OK.
    e. Click Exp. Date on the table header. The units will be arranged in the order of expiration date.
    f. Select print from TASK.
    g. Reconcile printout with physical units.
4. Perform **Transfusion administration audit monthly**.
5. Perform monthly maintenance on **Cellwashers -** check saline volume, inspect rotor and tube holders.
6. Perform monthly maintenance on **Serologic Centrifuges -** clean rotor, rotor shaft, and tube holders and re-grease rotor shaft and trunnions.

**C. Quarterly**

1. **Alarm Checks** of refrigerators, freezers, platelet incubator and RT. Refer to ***Alarm Check of Refrigerator Freezer and Platelet Incubator SOP.***
2. **Quarterly maintenance on refrigerators, freezers and platelet incubator/agitator**. Refer to the respective equipment SOPs for instructions.
3. Replace **backup batteries** (icon on electronic display) for the **CheckPoint** monitoring system on all refrigerators, freezers and platelet incubator if the **charge icon is less than half full**. Notify Engineering and BioMed (for Platelet Incubator only) to change the batteries (6 D batteries for each equipment).
4. **Centrifuge and Cellwasher RPM and Timer check** performed by Biomed Engineer.
5. **Electrical safety** of the refrigerators and freezers is checked by Engineering.
6. **Department specific disaster drill.**
7. **HELMER DH8 Plasma Thawer** quarterly maintenance performed by BioMed Engineer.

**D. Semi-annually**

1. Calibrate **pipettes**.
2. **Test method** comparison.
3. **ProVue** preventive maintenance performed by Ortho Clinical Diagnostic Field Engineer.

**E. Annually**

1. Check **coolers** for wear and tear.
2. **Calibrate thermometers** and **Log Tag** Temperature Recorders.
3. **Functional calibration** of **Serologic Centrifuges** and **Cellwashers**.
4. **Disaster Supplies** Inventory Check. Replace with new supplies that will not outdate until next annual check.

5. Backup **ProVue** configuration files, CQC, Defs, Plantillas.
6. Annual maintenance of **cell washers** by BioMed.
7. Annual replacement of **Checkpoint calibrated sensors/probes** by Engineering.
8. Print **Downtime Accession Labels** from LIS (Jan 1st).
9. Change **DI Water Filters** (service information can be found on the meter).
10. Check and replace **timers** prior to expiration of calibration.
11. HELMER **DH8** Plasma Thawer:
    a. Digital Thermometer Verification.
    b. Check the bearings on each basket for wear and replace if necessary **(performed by BioMed).**
12. **Blood Warmer** Calibration performed by BioMed.

**F. Quinquennially (every 5 years)**

1. The rotor (model 1126) and tube holders (model 1127) on EBA-21 Centrifuges must be replaced every 5 years (centrifuges were implemented on 2/6/2013).

**G. As needed**

1. Functional calibration of centrifuges at initial receipt and after major repairs.
2. Clean freezers' and refrigerators' condenser, interior, exterior and door gasket.
3. Clean exterior of Platelet incubator.
4. Initial validation of Temperature Indicators prior to implementation.
5. Replace rotor and tube holders of cell washers and centrifuges when worn or damaged.
6. Grease platelet agitator drive shaft.
7. Initial validation of new cooler prior to use.

**H. QC/Equipment Failure**

1. In the event of equipment failure or QC failure, notify the supervisor, place 'Out of Order' tag on equipment and:
    a. Do not report patient results unless it is determined that the test was not affected by the failure.
    b. For refrigerators and freezers - notify Facility Engineer. Take appropriate corrective action - refer to SFOWI-0034 Refrigerator Freezer Failure.
    c. For clinical laboratory instruments or devices e.g. platelet incubator, cellwashers, centrifuges - notify Biomed Engineer.
    d. For analyzers, call the manufacturer's technical support.
2. Supervisor will perform patient impact assessment and re-qualify equipment before it is returned to service.

**REFERENCE**

A. AABB, Standards for Blood Banks and Transfusion Services, current edition, Bethesda, MD.
B. AABB Technical Manual, current edition, Bethesda, MD.

## Associated Documents:

External Documents

BF0002 Blood Bank Quality Control Checklist
Transfusion Service QC/Maintenance/Validation Schedule
Associated Quality System Documents - None

## Documents Generated:

## Document Revision History:

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|---|---|---|
| **Revision:** 21 | **Date Created:** 09/12/2005<br>**Date of Last Revision:** 02/25/2019 | **Last Approval Date:** 01/31/2017 |

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| **Document Author:**<br>Cara H Lim/CA/KAIPERM | **Document Manager:**<br>Richard Chui/CA/KAIPERM |

## Reason for Change:

| Revision: | Sec/Para Changed | Change Made: | Date |
|---|---|---|---|
| 1 | N/A | Initial Issue of Document | |
| 2 | semi-annual maintenance | Change Helmer Freezer to as needed. | 12/3/06 |
| 3 | Approver | New Lab Director | 01/07/07 |
| 4 | Approver | New Lab Director | 07/29/07 |
| 5 | Procedure | A-1 Perform Alert Device activation check on Fridays.<br>E-3 Calibrate sensor in August by Check Point | 11/30/07 |
| 6 | Procedure D. Semi-annually | 10 samples for method comparison. If one discordant result test 10 more samples. Accept 95% agreement. | 11/22/08 |
| 7 | Procedure | Annually, functional calibrate centrifuges. | 12/14/08 |
| 8 | Procedure | Change antibody screen method comparison. Add clean plt incubator condenser quarterly. | 8/30/09 |
| 8 | Procedure | Change alarm check to wet ice and water. Add other plt incubator alarm check.<br>Changed annual maintenance | 3/7/10 |
| | Approver | Change Lab Director. | 6/1/11 |
| 9 | Procedure A.<br>Procedure B.<br><br>Procedure C.<br><br><br><br><br>Procedure F.4.<br>Procedure E.1.<br>Procedure E.6. | Added weekly check of Platelet agitator motion alarm.<br>Change frequency of Transfusion Audit from quarterly to bi-monthly.<br>Change frequency of Centrifuge and Cellwasher RPM and Timer check from semi-annually to quarterly. Added Platelet Incubator high and low alarm automatic and manual tests. Verify i.Center temperature monitor and and temperature controller reading.<br>Added validation of Temperature Indicators at receipt.<br>Changed Cooler validation form September to July.<br>Added grease agitator drive shaft and check battery backup on motion alarm of Plt Incubator. | 10/3/11 |
| 10 | Procedure D.2 | Added antibody panel comparison details. | 8/16/12 |
| 11 | Procedure<br>Procedure D.2.a.<br><br><br>Procedure A, B and E.<br>Procedure E.3. | Added NOTE.<br>Deleted using Daily reagent QC and Daily Provue QC for comparison to align with actual current practice. Change was recommended in last CPA inspection.<br>Added maintenance frequency for new cellwashers.<br>Changed from August to February. | 12/6/12 |
| 12 | Approver | New Lab Director | 1/17/13 |
| 13 | Procedure A.8., Procedure B.8.<br>Procedure F.<br>Procedure G.5.<br>Procedure B.5.g.<br>Procedure C.h.<br>Procedure E.8.<br>Procedure E.7.<br>Procedure E.1.<br>Procedure E.2.<br>Procedure E.3. | Added for new EBA 21 Centrifuge.<br>New.<br>New.<br>New.<br>New.<br>New.<br>Added November.<br>Changed from July to June.<br>Changed from Oct to Sept.<br>Changed from Feb to Jan and Dec. | 3/12/13 |
| 14 | Approver<br>Procedure C.4.& 5.<br>Procedure C.f.<br>Whole document<br>Procedure C.1.i. & C.6.<br><br>Procedure B.7., & 8.<br>Procedure F. | New BB Medical Director.<br>Added Mar,Jun,Sep,Dec.<br>Modified from 'check' to 'change'. Added to date the batteries.<br>Deleted TEG. No longer performing TEG.<br>New. Added to check backup batteries and safety check by Engineering.<br>Added descriptions of tasks.<br>Revised. Added descriptions of tasks. Changed | 8/7/13 |

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| | Procedure E.9.<br>Procedure B.6.<br><br>Procedure H.<br><br>Procedure C.1.a. and h. | implementation year from 2012 to 2013.<br>Added to print Downtime Accession Labels on Jan 1st.<br>Changed Blood Administration Audit from bi-monthly to monthly.<br>Added to place 'Out of Order' tag, not report patient test results and reference to SFOWI-0034.<br>Deleted wet ice method. | |
| 15 | Procedure E.<br><br>Procedure G.<br>Procedure C.1 & 2. | Moved backup batteries replacement from quarterly to annually.<br>Moved grease agitator drive shaft from annually to as needed.<br>Deleted instructions and added reference to Alarm Check SOP and equipment SOPs. | 3/13/14 |
| 16 | Procedure<br><br><br>Procedure A.4.<br><br>Procedure E. | Deleted months and added (NOTE) reference to Transfusion Service QC/Maint/Val Schedule instead to avoid conflict of information.<br>Deleted. Checking storage equipment temperature charts has been changed from weekly to daily QC task.<br>Moved replacing backup batteries from annually to quarterly. | 12/26/14 |
| 17 | Procedure C.9.<br>Procedure E.9.<br>Procedure E.10. | New. Added Dept. Disaster Drill to quarterly.<br>New. Added DI Water Filter Change as annual PM.<br>New. Added Timers replacement as annual PM. | 8/18/15 |
| 18 | Procedure A, C, & E | Added weekly, quarterly and annual maintenance for HELMER DH8 Plasma Thawer. | 11/14/15 |
| 19 | Procedure B and C.<br><br><br>Procedure G.4. | Deleted references to MT204 and MT210 due to Thermogenesis being replaced by Helmer DH8 Plasma Thawers.<br>Revised instructions from validating each new lot to validating the initial lot prior to implementation of temperature indicators. | 5/2/16 |
| 20 | Procedure A. Weekly<br><br>Procedure D. and E.<br>Procedure E. and G. | Added 'Perform weekly backup of Access database for Blood Bank Specimen Problem and Product Wastage'.<br>Changed Blood Warmer from semi-annually to annually.<br>Changed Cooler validation from annually to as needed. Replace with annual cooler check for wear and tear. | 11/2/16<br><br><br>1/12/17 |
| 21 | Procedure A.6. | Deleted 'Serologic'. | 2/25/19 |

## Notification List:

## Approvals:

**First Approver's Signature**

**Name:** Sarah C Cherny/CA/KAIPERM
**Title:** Transfusion Service Medical Director

**Second Approver's Signature**

**Name:** Elizabeth M Hosfield/CA/KAIPERM
**Title:** Chief of Pathology; CLIA Director

**Document History Section**