




Kaiser Permanente Medical Center, San Francisco
Northern California Region

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|  Work Instruction | | |
| Title: TS-Receipt and Storage of Blood Components | WI Number SFOWI-0067 Revision: 13 | |
| Department: Immunohematology | Document is in the Final Approval Process. 2 - approvals are required | |
| Area: 2425 Geary Blvd SFO Hospital Lab | | |
| Type of Document: Work Instruction | | Review Period - 340 Days |

PURPOSE

To eliminate errors in the receipt of blood and blood components, it is necessary to initiate a procedure for the checking and proper storage of all components coming into the blood bank. These procedures are to be followed by all shifts.

PROCEDURE:

A. Blood Product Receipt

1. Make sure that the blood products have been appropriately packed for shipment by the supplier.
 - a. Frozen blood products are packed with dry ice.
 - b. PRBCs are packed with ice packs. Ice packs should still be frozen upon arrival.
 - c. Platelets are packed with room temperature stabilizing gel packs.

2. **Computer Entry**
 - a. Enter all the units in the Transfusion Service computer system.
 - b. Scan each barcode on the unit face label into its corresponding field in LIS e.g. DIN, ABORh, Ecode and expiration date. **Important:** These 4 fields cannot be manually entered or selected from the drop down menu. If the Ecode is not found in the LIS, return unit to supplier unless unit is special. In this case, select the closest product description from the drop down menu and inform RN that unit cannot be scanned into BPAM.
 - c. Enter the special requirements such as CMV-, HgbS-, Irradiated or Antigen confirmed to be negative.
 - d. Enter volume if it does not auto populate.

 - e. **Visual Inspection**
Visually inspect each unit as it is being entered for the following:
 - i. Each unit is intact and not broken or leaking.
 - ii. Red cells units are not dark purple/black in color or have clots (all evidence of possible bacterial contamination).

- iii. Unit is not discolored and hemolyzed.
- iv. RAD-SURE 25 Gy indicator must show IRRADIATED on irradiated products.
- v. Direct Donated units, HLA and Crossmatched platelets are irradiated.
- vi. All labels are intact, complete and legible.
- vii. No more than two unique numeric or alphanumeric donor identifications.

f. **Directed/Autologous Units (also refer to SFOWI-0099 Autologous and Designated Transfusion)**

These units arrive at anytime and they should be entered in the computer immediately.

- i. Make sure the name, MR#, date of birth/Social Security Number on the unit tag matches the information in *all* computer systems.
 - ii. Make sure DD units donated by blood relative are irradiated.
 - iii. Enter patient in the Transfusion Service computer system if patient is new.
 - iv. If the intended surgery/transfusion date is today or tomorrow, set up DD or autologous units to replace random units.
 - v. Enter in computer system and reserve on the intended recipient's MR#.
 - vi. Store designated donor units on the 'Designated Donor' shelf after type confirmation.
 - vii. Place autologous units on the 'Unconfirmed Autologous' shelf which is segregated from the random units.
 - viii. Print out a new Directed/Autologous inventory report.
 - ix. Post this list on the AUTO/DD clipboard.
 - x. Reserve Autologous, DD and Crossmatched or HLA matched platelets on the patient upon receipt.
- g. Check the automatic printed Product Receipt Report against the shipping document for agreement of unit information and the number of blood products received equals to the number of units received in computer.
- h. Initial to indicate acceptable visual inspection and no clerical discrepancy.

B. Problems/Discrepancy

- 1. Notify blood supplier immediately of the following:
 - a. Any discrepancy between the units received and the shipping document.
 - b. Abnormal appearance, broken bag, no segments and any labeling errors.
 - c. DD unit donated by blood relative was not irradiated.
 - d. RAD-SURE 25Gy sticker did not turn black.
 - e. Products were inappropriately packed for shipment.
- 2. Return unit to blood supplier after receiving and then final disposing unit in LIS indicating the reason.

C. Storage

- 1. Red cells received are stored on the 'Unconfirmed Units' shelf in the refrigerator.
- 2. FFP and cryoprecipitates are stored in the appropriate shelves matching their ABO type in the freezer.
- 3. Platelets are stored in the platelet incubator.
- 4. Unauthorized personnel are prohibited access to the blood storage refrigerators, freezer and platelet agitator.

5. The shelf life or expiration dates and storage temperature for all blood components comply with 21CFR 610.53 and the manufacturer's recommendations.
See Table A.
6. Storage temperature of refrigerators, freezers, platelet incubator, and ambient environment is continuously monitored by Checkpoint, a computerized system that records temperature and alerts when temperature is out of range.

Table A.

| Components | Shelf Life | Storage Temp |
|---|---|--------------------------|
| Red blood Cells ACD/CPD/CP2D | 21 days | 1-6 °C |
| Red blood Cells CPDA-1 | 35 days | 1-6 °C |
| Red blood Cells Additive Solution | 42 days | 1-6 °C |
| Red blood Cells Open System | 24 hours | 1-6 °C |
| RBC Leukoreduced ACD/CPD/CP2D | 21 days | 1-6 °C |
| RBC Leukoreduced CPDA-1 | 35 days | 1-6 °C |
| RBC Leukoreduced Additive Solution | 42 days | 1-6 °C |
| RBC Leukoreduced Open System | 24 hours | 1-6 °C |
| Whole Blood ACD/CPD/CP2D | 21 days | 1-6 °C |
| Whole Blood CPDA-1 | 35 days | 1-6 °C |
| Whole Blood Open System | 24 hours | 1-6 °C |
| RBC Irradiated | Original expiration or 28 days from irradiation | 1-6 °C |
| RBC Deglycerolized | 24 hours | 1-6 °C |
| RBC Rejuvenated | 24 hours | 1-6 °C |
| RBC Washed | 24 hours | 1-6 °C |
| Platelets Pheresis Leukoreduced | 5 days | 20-24 °C with agitation |
| Platelets Pheresis Leukoreduced Irradiated | 5 days | 20-24 °C with agitation |
| Washed platelets | 4 hours | 20-24 °C with agitation |
| Volume reduced/Dry platelets | 4 hours | 20-24 °C with agitation |
| Platelet Pheresis Open System | 4 hours after opening | 20-24 °C with agitation |
| Fresh Frozen Plasma | 1 year | -18 °C or lower |
| Plasma Frozen 24 hours of collection | 1 year | -18 °C or lower |
| Thawed FFP | 24 hours | 1-6 °C |
| Thawed Plasma | 5 days after thawing | 1-6 °C |
| Thawed Pedi FFP & Thawed Plasma of open system | 24 hours after thawing | 1-6 °C |
| Cryoprecipitate Reduced Frozen Plasma | 1 year from collection | -18 °C or lower |
| Cryoprecipitate Reduced Thawed Plasma Open System | 24 hours after thawing | 1-6 °C |
| Cryoprecipitate Reduced Thawed Plasma | 5 days (closed system) | 1-6 °C |
| Cryoprecipitate AHF Frozen | 1 year from collection | -18 °C or lower |
| Cryoprecipitate AHF Thawed | 6 hours | 20-24 °C w/ no agitation |
| Cryoprecipitate AHF Pooled Thawed | 4 hours | 20-24 °C w/ no agitation |
| Granulocytes | 24 hours from collection | 20-24 °C w/ no agitation |

D. Quarantine

1. Any unit discovered during storage to be abnormal in appearance such as clotted,

hemolyzed or has missing/illegible labels that requires supervisory review.

- a. Quarantine the unit in computer.
- b. Place on quarantine shelf.

E. Return to Blood Supplier

1. Per blood supplier request.
 - a. Fill out the appropriate blood supplier return form and indicate reason for return.
 - b. Set the unit(s) aside on the shelf labeled 'Return to Blood Supplier'.
 - c. Return to Supplier in LIS when the unit is picked up.
2. Return short dated platelet pheresis using the appropriate blood supplier return form.
 - a. Final dispose unit in LIS using Reason: 'Return to Supplier' and Method: 'Return to Supplier'.
 - b. Pack appropriately in a platelet cooler/box.
 - c. Prepare voucher and call a taxi to transport the cooler to blood supplier.
3. Save a copy of the return form and attached it to the LIS printout.

PROCEDURE NOTE(S)

- A. Frozen blood components are thawed at 30 - 37 °C.
- B. Maximum time without agitation allowed for platelets is 24 hours.

REFERENCE

AABB, Standards for Blood Banks and Transfusion Service, current edition, Bethesda, MD.

Associated Documents:

External Documents

Associated Quality System Documents - None

Documents Generated:

Document Revision History:

| | | |
|--|---|---------------------------------------|
| Revision: 13 | Date Created: 09/21/2005 Date of Last Revision: 05/01/2018 | Last Approval Date: 09/09/2016 |
| Document Author: Cara H Lim/CA/KAIPERM | Document Manager: Richard Chui/CA/KAIPERM | |

Reason for Change:

| Revision: | Sec/Para Changed | Change Made: | Date |
|-----------|------------------|---|----------|
| 1 | N/A | Initial Issue of Document | 9/21/05 |
| 2 | Approver | New Lab Director | 01/01/07 |
| 3 | Procedure E | Clarify return to BCP procedure | 4/15/07 |
| 4 | Approver | New Lab Director | 7/1/07 |
| 5 | Procedure | Delete 7 day and pooled platelets | 11/15/08 |
| 6 | Procedure | Delete RILIS function. Added 5-day plasma. Updated Lab Director | 6/1/11 |
| 7 | Procedure | Storage shelf life(Expiration date) complies with FDA requirements. | 1/1/12 |
| 8 | Approver | New Lab Director. | 5/8/13 |

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|----|--|--|---------|
| 9 | Approver Procedure A.1.a. to c. Procedure A.2.h. Procedure C.6. Procedure A.2.f. | New BB Medical Director. Added to check for appropriate shipment packing. Added visual inspection. New. Added Checkpoint continuous temperature monitoring. Added reference to SFOWI-0067. | 8/1/13 |
| 10 | Procedure C. Table A. Procedure Notes B. | Added Platelet Pheresis Open System expiration as 24 hours. Revised Thawed Plasma expiration to 5 days and Thawed FFP to 24 hours. New. Added 24 hours as maximum time acceptable for platelets without agitation. | 8/12/15 |
| 11 | Procedure E. | Updated BCP forms. | 5/2/16 |
| 12 | Approver | New CLIA Director. | 9/8/16 |
| 13 | Procedure A.2. | Revised due to BPAM implementation scheduled 3/20/18. Added NOTE that the 4 major barcodes i.e.DIN, ABORh, Ecode and Exp date on unit face label must be scanned and not manually entered. | 3/6/18 |

Notification List:

Approvals:

First Approver's Signature

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Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
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Document History Section