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Procedure: Platelet Preparation for Issue

I. PURPOSE

To detail procedure for preparing platelet apheresis suitable for issue.

II. SCOPE

This SOP addresses procedure for preparation of platelet aliquots and product labeling. This applies to all trained blood bank team members.

III. STATEMENTS/REQUIREMENTS

A. Leukocyte Reduced Apheresis Platelets: All platelet products received at IUH Blood Bank are Leukocyte Reduced Apheresis platelets.

B. Bacterial Contamination Risk Reduction - All platelet products are either:

1. Tested for bacterial contamination by the supplier, OR
2. Manufactured using an FDA-approved Pathogen Reduction Technology.

C. Universal Irradiation of Platelet Products:

1. PRT products do not require irradiation.
2. All non-PRT platelets received at IUH will be irradiated prior to transfusion.
3. Exceptions must be approved by a Blood Bank Physician.

D. Infants and Children ≤ 40 Kg Platelet Transfusion

1. Must receive ABO compatible and Rh appropriate platelets, when available.
2. Female infant/children who are Rh negative should receive Rh negative platelet products when available.
3. Exceptions of more than two Rh positive platelets in 24 hours must be approved by a Blood Bank Physician.

E. Rh Negative Platelet Usage:
   1. Female patients greater than 4 months of age and less than or equal to 50 years of age who are Rh negative should receive Rh negative platelet products.
   2. Exceptions of more than two Rh positive platelets in 24hrs must be approved by a Blood Bank Physician

F. Product(s) with visible contamination of donor red cells are not used. These products are to be returned to their respective Blood Center.

G. Platelets must be stored:
   1. at 20-24°C.
   2. on platelet agitator in platelet incubator.

H. Platelet Expiration dates:
   1. Platelet Apheresis (closed system) = original expiration.
   2. Platelet Apheresis (open system) = 4 hours.
   3. Non-Platelet transfer bag = 24 hours or original expiration whichever is first.
   4. Double Bag Platelet Apheresis = 24 hours or original expiration, whichever is first once platelets are combined/pooled in 1 bag.

I. Diagnosis: Neonatal Alloimmune Thrombocytopenia
   1. If the infant's mother donates a platelet for the infant, then the platelet will be washed before transfusion. See SOP Washing of Blood Components: COBE 2991.
   2. If maternal platelets are not an option, then platelet antigen matched platelet products (example: PLA1 negative platelets) may be obtained from the donor center

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

CMV: Cytomegalovirus

DIN: Donation Identification Number

FDA: Food and Drug Administration

HLA: Human Leukocyte Antigen

ISBT: International Society of Blood Transfusion

NAIT: Neonatal Alloimmune Thrombocytopenia

PRT: Pathogen Reduction Technology

SCD: Sterile Connecting Device

SOP: Standard Operating Procedure

TD: Transfusion Document

V. EQUIPMENT/RESOURCES

Apheresis platelet product Quad pack bags/transfer bags

Tubing Sealer

Plasma transfer tubing set

Sterile Connecting Device (SCD)/QC Log

Labels (base label, ABO/RH, product, aliquot tracking, special attributes, expiration, storage temperature)

Balance (scale)

VI. PROCEDURE

A. Review Blood Product Order/Request and Select the Appropriate Platelet Product:

1. Select platelet product based on ABO/Rh compatibility:

   a. ABO group: See Table 1

   Table 1: "Guidelines for selection of appropriate ABO group for transfusion"

Patients ABO Group	Donor ABO Group			
	1st Choice	2nd Choice	3rd Choice	4th Choice
A	A	AB	(B)	(O)
B	B	AB	(A)	(O)
AB	AB	(B)	(A)	(O)
O	O	A	B	AB

   Blood groups in parentheses represent choices with incompatible plasma.

   b. Use of ABO Incompatible Platelets:

      i. No more than 2 ABO incompatible platelet units per day (24 hours) will be issued per adult patient.

      ii. Blood Bank Physician must approve any use of ABO Incompatible Platelets when it exceeds 2 out-of-type platelet unit within a 24-hour period. **EXCEPTION**: Trauma and excessively bleeding patients.

   c. Rh Type:

      i. If patient is Rh positive, an Rh negative male, or an Rh negative female greater than 50 years of age, then Rh positive platelets may be given.

      ii. If the patient is Rh negative and female less than 50 years of age, then whenever possible give Rh negative platelets.

         1. If Rh negative platelets are not available, then these patients may receive up to two Rh positive platelets within a 24 hour period. Additional Rh positive platelets may be given with approval from a Blood Bank Physician.

         2. Exception: trauma patients or rapidly bleeding patients do not require approval from a Blood Bank Physician.

2. Special Transfusion Requirements: Cerner Computer Flags and/or Clinician request.

   a. CMV Negative - PRT platelets may be issued without the CMV-barcode.

   b. Irradiated - PRT platelets do not require irradiation.

   c. Washed; May only be given with a Blood Bank Physician Consultation/Approval.

3. Volume Requested

   a. If an aliquot is requested, use platelet products reserved for aliquoting.

   b. If a partial product is required (half unit), use product that has at least 24 hour expiration to maximize transfusion of remaining product.

4. Expiration Date/Time

a. To maximize the available product inventory, preference for product selection is given to transfusing the oldest available product that meets the patient's transfusion requirements.

b. Product expiration date/ time:

i. Single bags: original expiration

ii. Double bags (combined): 24 hours (closed system) or original expiration (whichever is first)

iii. Open system: 4 hours

5. Special Platelet Requests for HLA-matched Products

a. If there is a unit available in inventory for the patient, release it to the floor.

b. If there is NO unit available in inventory for the patient, contact on-call Blood Bank physician for further instructions.

c. Do NOT order HLA-matched platelets from the donor center without Blood Bank MD or management approval.

d. Cerner PPI entries when HLA-matched platelets are ordered from the donor center:

i. Add Transfusion Requirement "HLA-matched Plt".

ii. Add PPI comment "HLA-matched platelets approved by <BB MD name who gave approval>

e. Complete the Monitor Log for Special Platelet Requests when product arrives.

B. Component Modification of Platelet Product

1. Pooling/combining Double Bag Platelet Apheresis:

a. Open integral clamps between platelet bags, transfer contents from one bag to the other.

b. Double seal tubing adjacent to bag containing platelets and detach empty bag.

c. Correct the expiration date/time to 24 hours after bags have been combined when closed system is maintained or original expiration (whichever is first).

d. Perform Cerner computer entries. See section C.

e. Label and Assign products. See sections D and E.

2. Aliquoting Platelet Apheresis:

a. All aliquots should be:

i. CMV negative.

ii. Irradiated.

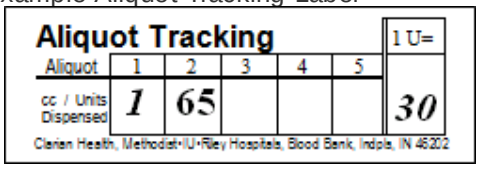
iii. **OR** manufactured using PRT in lieu of CMV negative and irradiated.

b. Follow steps in section A.

c. Apply green aliquot tracking label on original apheresis bag.

i. Enter volume of platelet on aliquot tracking label in space provided.

ii. Example Aliquot Tracking Label



d. Aliquot:

i. Affix a DIN to the transfer bag.

ii. Record required information on Form: Sterile Tubing Welder Worksheet.

iii. Using SCD - Attach transfer bag to original platelet apheresis bag.

iv. Allow desired volume of platelets to flow into transfer bag and record in next box of aliquot tracking label platelet equivalent associated with that volume.

v. Seal tubing to transfer bag, leaving a segment for future testing.

vi. Perform Cerner computer entries. See section C.

vii. Label and Assign products. See sections D and E.

viii. Have 2nd technologist review labeling and initial Form: Sterile Tubing Welder Worksheet.

C. Cerner Applications

1. Modify LAPL to **(new product)** Refer to SOP BBCE-006 Modify Products for additional instructions:
   a. Platelet Aliquot
   b. Note: Perform "**DIV PLT**" in "**Modify Products**" when preparing the 1st aliquot.
   c. Select: "**Modify Product**" icon
      i. Option "**ALIQ PLT Ped**" (ISBT units)
      ii. Option "**ALIQ DD PLT Ped**" (Directed Donor ISBT units)
   d. Original Products: Barcode or manually type DIN and Product Code. If product was previously aliquoted, select the original container from "**Selected Product(s)**" menu.
   e. New Product: Sub ID/Aliquot ID will generate
   f. Change volume **"0"** to desired volume.
   g. <**SAVE** >
   h. ISBT Products will generate a new product label
      i. Apply product label to aliquot. Follow steps in Section D.
      ii. Verify label using "**Label Verify**" icon. See SOP Label Verify.
2. Pooling/Combining Double Bag Platelet Apheresis
   a. Select in "**Correct Inventory**" icon the "**Demographics**" tab
   b. Original Products: Barcode or manually type DIN
   c. Modify old Expiration Date/Time to the new Expiration Date/Time
      i. Closed system: 24 hours from combining or original expiration, whichever comes first.
      ii. Open System: 4 hours from combining or original expiration, whichever comes first.
   d. Re-label product with the new Expiration Date/Time.
3. Attaching/ Removing CMV Attribute. Refer to SOP Modify Products for additional instructions:

D. Labeling of Modified Platelet Products.

1. A Product Label, with the minimum information required, is attached to all splits or aliquots from the Primary Container. Minimum information attached:
   a. **Base label**. A product label will be generated by the system at the time of product modification. Extra labels may be required to be applied to make a complete product label.
   b. Donor Number
   c. **Donor ABO/Rh**

d. **Component name**

e. **Applicable special attribute sticker** (i.e., CMV Neg, Irradiated, Leukoreduced)

f. Expiration date/time

g. **Product volume**

h. **Anticoagulant volume**

i. "**DO NOT REFRIGERATE**" or **"STORE AT ROOM TEMP"** label

2. ISBT product labels with modified Date/Times may be reprinted in Cerner. See SOP Generate Tags and Labels.

3. **"Label Verify"** all ISBT modified products in Cerner. Refer to SOP Label Verify.

4. Assign modified product to patient, generate Transfusion Document, and attach to the modified product with a secure tie. Follow steps section E.

5. Second Tech Check of all labeled aliquots/splits is made prior to dispensing of the product.

   a. The Second tech will review the original product label against the modified product label to ensure that they match.

   b. The Second tech will review the modified product label to ensure that any additional modifications/attributes made to product is also reflected on the product label (e.g., Expiration Date/Time).

   c. The Transfusion Document will be compared to the modified product label and Product Order to ensure it also accurately reflects the necessary modifications/attributes that are stated.

   d. The tech will initial the correct column on the SCD log to document the second check was made on this product.

E. Assigning Platelet Products:

1. Products may be assigned to the patient using "**Modify Products**" icon. Refer to SOP Modify Products. Additional instructions on assigning products can be found in SOP Procedure: Dispense and Assign Products.

2. Use the "**Dispense and Assign Products**" icon to assign products to the patient.

   a. Select the proper platelet product ensuring that the product meets all special patient requirements and meets the stated needs of the Product Order.

   b. Select "**Dispense and Assign Products**" icon:

   c. Select the "**Assign**" task button

   d. Type in the patient's MRN.

   e. Press "**ENTER**" key.

   f. Select the correct current encounter, which is noted under "Fin#:" on Product Order.

   g. "Preadmit" encounter may be used for patients admitted for surgery or other procedures.

   h. Barcode or manually type DIN/Product Code for selected product.

   i. <**SAVE**>

   j. Select correct Medical Indication for transfusion under "**Reason**" box.

   k. Select: <**OK>**

   l. TD will print.

3. Attach TD to product

a. Confirm product DIN matches DIN on TD.

b. Confirm Product Code matches Product Code on TD.

c. Confirm TD Patient Information matches that on patient Product Order.

d. If Patient Blood Type and Product Blood Type differ, put "Donor Type Differs from Patient OK___" label on TD and initial the label.

e. Attach TD to product with a secure tie.

4. Store Assigned products.

   a. Place modified products and original products on platelet rotator.

   b. Use tape and a marking device to write patient's name, to identify product for patient on the rotator.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition

AABB Standards, current edition

Quality System, IU Health.

IX. FORMS/ APPENDICES

None

X. APPROVAL BODY

None

PROCEDURE #:

BBCP – 004