TRAINING UPDATE

Lab Location:

SGAH

Date Implemented:

5.16.2013

Department:

Blood Bank

Due Date:

5.20.2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Volume-Reduced and Saline-Replaced Platelet Products

Description of change(s):

- Updated SOP to include ISBT-128 instructions.
- Added summary of process above procedure in SOP.
- Added emphasis that a platelet aliquot must be made (physically and in LIS) prior to performing the volume-reduction procedure.
- Blood component prep code for all concentrated (volume-reduced) products will be "C" plus the E code. For example, if you concentrate product E3046, your BCP code will be CE3046.
- We must print new blood product labels for concentrated products using the HemaTrax system (training in progress).
- There are no codes for Saline-Replaced platelets. Please continue to use the tie tag per previous procedure.
- Sunquest v6.3 CANNOT recognize the division letter for an aliquotted ISBT-128 product. If you concentrate a platelet aliquot, print the slash number label from Sunquest and apply it to the ISBT label as for all aliquotted products.

Non-Technical SOP

| Title | Volume-Reduced and Saline-Replaced Platelet Products | | |
|-------------|--|-----------------|--|
| Prepared by | Stephanie Codina | Date: 3/16/2011 | |
| Owner | Stephanie Codina | Date: 3/16/2011 | |

| Laboratory Approval | | | |
|---|-----------------------|------|--|
| Print Name and Title | Signature | Date | |
| Refer to the electronic signature page for approval and approval dates. | | | |
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| Local Issue Date: | Local Effective Date: | | |

| Review: | | | | |
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1. PURPOSE

This procedure describes the process for preparing volume-reduced (plasma-removed) and saline-replaced platelet products. Volume-reduced and saline-replaced platelets are generally prepared for infant and pediatric patients. However, they may also be prepared for adult patients in certain situations. Volume-reduction of platelets is achieved by centrifugation and subsequent removal of a portion of the plasma. Saline-replacement is achieved by adding saline to the volume-reduced platelet product.

2. SCOPE

Volume-reduced platelets may be necessary for patients at risk of volume overload or for neonatal or pediatric patients who cannot tolerate incompatible plasma in out-of-group platelet products.

Saline-replaced platelets are indicated for patients who have experienced multiple progressive allergic reactions to plasma products.

3. RESPONSIBILITY

All blood bank staff must demonstrate competency in preparing volume-reduced and saline-replaced platelet products.

4. **DEFINITIONS**

N/A

5. PROCEDURE

Summary of steps that will be performed in this procedure

- A. Physically prepare a platelet aliquot.
- B. Irradiate the aliquot.
- C. BCP the aliquot in the LIS to generate a slash unit (use A + E code).
- D. Physically volume-reduce the aliquot.
- E. BCP the volume-reduced aliquot in the LIS (C + E code).
- F. Generate a HemaTrax label for the aliquot.
- G. Allocate/issue the aliquot using the slash unit number.
- H. BSU the salvage plasma and discard.

Select a Platelet Product

| Step | Action | | | |
|------|---|--|--|--|
| 1 | Apheresis platelet products intended for transfusion in neonates and pediatric patients must meet the following criteria: A. Group specific or group AB. a. Do not transfuse any AB platelet product that is visually contaminated with red cells. b. Any group of platelets may be transfused to a neonate/pediatric patient if the volume-reduction procedure has been performed. B. Rh-negative females of child-bearing age or younger (<50 years old), should receive Rh-negative platelets. In emergency situations where Rh-negative platelets are not available, these patients may receive Rh-positive platelets with pathology approval. C. CMV-seronegative (only required for infants less than 4 months in age and patients with CMV attribute markers in their blood bank files) D. Irradiated (only required for infants less than 4 months in age and patients with irradiated attribute markers in their blood bank files) | | | |

Preparing Volume-Reduced (Concentrated) Platelets

| Step | Action | | | | |
|------|--|--|--|--|--|
| 1 | The equipment required to perform a platelet concentration and volume- | | | | |
| | reduction is: | | | | |
| | A. RC-4 centrifuge | | | | |
| | B. Sterile Welding Device | | | | |
| | C. Blood Irradiator | | | | |
| | D. Hematron heat sealer or metal clips and a hand sealer | | | | |
| | E. Scale | | | | |
| | F. Sterile transfer pack | | | | |
| | G. Hemostats or clamps | | | | |
| | H. Plasma Expresser | | | | |

| Step | Action |
|------|--|
| 2 | Set the RC-4 centrifuge temperature dial between 20° – 24° C. A. Assure the internal temperature is at least 20°C prior to centrifugation. B. Document the temperature on the temperature QC record. C. If the temperature is below the acceptable range, run the centrifuge through one spin cycle can increase the temperature. |
| 3 | Volume-reduction can be performed on the following: A. An apheresis platelet product if the product is being prepared for an adult or larger child. B. A platelet aliquot if the product is being prepared for a neonate or smaller child. |
| | Prior to beginning, A. Aliquot the platelet product if a low-volume product is requested for a neonate or small child. a. You must prepare the platelet aliquot in a pediatric bag (do not use a syringe) prior to performing the volume reduction process. b. You must complete preparation of the aliquot physically and in the computer prior to beginning the volume-reduction process. c. Refer to procedure, "Platelet Aliquot Preparation." B. Irradiate the product per procedure, "Blood Component Irradiation." You must complete the irradiation process physically and in the computer before beginning the volume-reduction process. |
| 4 | Weld a 150 ml transfer bag to the appropriately labeled apheresis bag or aliquot bag (refer to procedure "Sterile Tubing Welder." It will be used to collect the salvage plasma after centrifugation. Do not break the weld seal at this time. |
| 5 | Obtain the weight of the platelet product and prepare a centrifuge balance. A. Perform and document scale quality control on the Scale Calibration and QC form. B. Place the platelet product in a plastic centrifuge bag and weight. C. Assemble a centrifuge balance bag for the platelet unit. |
| 6 | Place the unit with the satellite bag in an upright position in a centrifuge bucket. Balance the centrifuge with the balance bag. |
| 7 | Centrifuge the platelets at 20° –24° C at 2000 RPM's for 10 minutes. |

| Step | Action | | | |
|------|--|--|--|--|
| 8 | Volume-reduce the platelet. | | | |
| | A. Remove the platelet bag from the centrifuge, being careful not to | | | |
| | disturb the contents of the bag. | | | |
| | B. Place the bag with the platelets onto the plasma expresser. | | | |
| | C. Calculate the volume of plasma to be removed based on the volume of | | | |
| | platelets requested. Be sure to add 5mL for tubing. | | | |
| | a. Volume Removed (mL) = Initial Volume - Desired Volume + 5 (for tubing) b. Desired volume = the volume requested by the physician. If the physician | | | |
| | does not designate the volume, remove approximately 70% of the plasma. | | | |
| | D. Place the salvage plasma bag onto the scale. | | | |
| | E. Tare the scale with the bag in place. | | | |
| | F. Express the calculated amount of plasma. | | | |
| | G. This removed plasma will be discarded. | | | |
| | H. The product for transfusion will be the bag with the pellet. | | | |
| 9 | Use a hemostat to clamp the tubing temporarily, then permanently seal the | | | |
| | tubing using a metal clip. Heat seal the tubing between the platelet and the | | | |
| | expressed plasma. DO NOT separate the connection unless the aliquot is | | | |
| | properly labeled. | | | |
| 10 | Perform the LIS function to volume reduce the platelets. | | | |
| | A. Access Sunquest function, "Blood Component Preparation." | | | |
| | B. In the "Lookup by" field, select "Component Prep Function." | | | |
| | C. In the value prompt, type the correct blood component preparation | | | |
| | function and press the "Tab" key. Refer to appendix A for details. | | | |
| 1 | D. Press the tab key twice to default the current date and time. | | | |
| | E. Click on the "Continue" button. | | | |
| | F. At the "Unit Number" prompt, barcode the unit number from the unit to be volume reduced. | | | |
| | | | | |
| | G. Select the correct component type from the dropdown list if the field does not autofill. | | | |
| | H. Press the "tab" key. | | | |
| | I. The message "Component type does not match maintenance | | | |
| | definitions. Continue?" will appear. Click the "OK" button. | | | |
| | J. Type in the new volume of the volume-reduced platelet in the "PLV | | | |
| | Volume" field. | | | |
| | K. Correct the product expiration date and time. The product will expire 4 | | | |
| | hours from the time the product was prepared or the expiration of the | | | |
| | parent product/aliquot (whichever is sooner). | | | |
| | | | | |

| Step | A chiam | | | |
|------|---|--|--|--|
| 10 | Action L. Return to the task tree and double-click the yellow N associated with | | | |
| Cont | the salvage plasma (SLV). Type in the volume of plasma to be discarded in the "SLV" volume field. Note: The SLV and PLV su should equal the volume of the original platelet aliquot. If a 50 mL aliquot is volume-reduced to 15 mL of concentrated platelets, the volume of concentrated platelets should be 35 mL. M. Click on the "Save" button. N. The popup "File all units?" will appear. Click the "OK" button. O. An "Output / New Units" screen will appear. Click the "Close" but | | | |
| | Marcifer (second Prep) Congame Prep Fundan Fox (MITA) Congame Prep Fundan Fo | | | |
| | Teal | | | |
| | The first control of the control of | | | |
| 11 | Generate a new label for the volume-reduced (concentrated) product using the HemaTrax system. Refer to procedure, "ISBT-128 Label Production" for guidance. Be sure to add the slash label number of the platelet from the Sunquest system. | | | |
| 12 | Discard the salvage plasma in the LIS. A. Access Sunquest function "Blood Status Update." B. At the "Update Option" prompt, select "Unit Update" from the dropdown list. | | | |
| | C. At the "Unit #" prompt, type in the unit number of the salvaged plasma (this should have a /#).D. Select the component "SLV" from the dropdown menu and press the "Tab" button. | | | |
| | E. Press the "Tab" button twice to default the current date and time.F. At the "New Status" prompt, type "DS" or select "Discarded, Incinerated" from the dropdown menu. | | | |
| | G. In the "Reason Code" prompt, type "SALVP" for "Discard plasma, incinerated."H. Click the "Add" button.a. Click the "Save" button. | | | |

| Step | Action | | | |
|------|--|--|--|--|
| 12 | Discard the expressed plasma in the biohazard trash. | | | |
| Cont | | | | |
| | Proceed to step 13 if saline-replacement will be performed and step 14 if only | | | |
| | volume-reduced platelets have been requested. | | | |
| 10 | | | | |
| 13 | If saline-replacement has been requested (do not perform this step if | | | |
| | volume-reduced or concentrated platelets have been requested): | | | |
| | A. Aseptically attach a double-cannula transfer tubing to the platelet bag | | | |
| | via a port. | | | |
| | B. Aseptically spike a bag of pharmaceutical-quality sterile 0.9% saline | | | |
| | with the other end of the transfer tubing. Allow an appropriate amount | | | |
| | of saline to flow into the platelet bag. | | | |
|] | a. Add 10-15mL of 0.9% saline to a neonate/pediatric aliquot. | | | |
| | b. Add 100mL of 0.9% saline to an adult platelet. You may need to obtain saline from pharmacy. | | | |
| | C. Temporary clamp the line using a hemostat. Attach a metal hand sealer | | | |
| | clamp to the tubing near the platelet bag. Heat seal the tubing using the | | | |
| | heat sealer. Discard any remaining saline. | | | |
| 1 | D. Document the manufacturer, lot number, and expiration date of the | | | |
| | saline used in the LIS. | | | |
| | a. Access Sunquest function, "Blood Product Entry." | | | |
| | b. Click on the "Modify Unit" button. | | | |
| | c. Scan or type the unit number at the "Unit #" prompt. | | | |
| | d. Scan or type the collecting facility if prompted to do so. | | | |
| | e. At the "Component" prompt, select the correct component from | | | |
| | the dropdown menu. | | | |
| | f. Click the "OK" button. | | | |
| | g. Click on the "Comments" folder. | | | |
| | h. In the "freetext" area, type in the saline manufacturer, lot | | | |
| | number, and expiration date. Example: | | | |
| | "Baxter saline lot P256305 expires 08/2011" i. Click the "Add" button. | | | |
| | j. Click the "Save" button. | | | |
| | E. Attach a tie-tag to the unit indicating it is a "Volume-Reduced Saline- | | | |
| | Replaced Platelet Product." | | | |
| | | | | |

| Step | Action | | |
|------|---|--|--|
| 14 | Have a second tech verify the labeling of the blood product and document the 2 nd label check on the "Product Modification Log" form. The following will be verified. Do not issue the product if discrepancies exist. A. Unit number of DIN B. Divided unit slash number (53FC##### / 1) or division letter if an aliquot was made prior to plasma removal C. ABO/Rh D. Intended use (volunteer or directed donor) E. Donation type (volunteer or directed donor) F. E product code and description G. Expiration date and time H. Special testing (if applicable) I. Facility information J. Volume of the aliquot | | |
| 15 | Allow the platelets to rest without agitation at room temp. (20° –24°C) for a minimum of 1 hour. | | |
| 16 | After the 1 hour rest, gently resuspend the platelets by mixing gently by hand to attain a uniform suspension. Then place the platelets on the platelet rotator $(20-24^{\circ}\text{C})$ with continuous agitation until the product is issued. | | |
| 17 | Platelets should be inspected before issue to ensure that no platelet aggregates are visible. | | |
| 18 | Allocate the platelet using Sunquest function "Blood Order Processing." Freetext the unit tag comment: A. For irradiated, volume-reduced platelets ";;Product is concentrated and irradiated." B. For irradiated, saline-replaced platelets ";;Product is irradiated and concentrated and xxxmL of saline has been added." C. For volume-reduced platelets, ";;Product is concentrated." D. For saline-replaced platelets ";;Product is concentrated and xxxmL of saline has been added." | | |
| 19 | Issue per procedure. A. The product should be transfused as soon as possible. B. Transfusion should take place with a blood component recipient set. | | |

6. RELATED DOCUMENTS

SOP: Platelet Aliquot Preparation SOP: Sterile Tubing Welder

SOP: Scale Quality Control

SOP: ISBT-128 Label Production

Form: Blood Bank Scale Calibration and QC Form

7. REFERENCES

- Roback, J.D., Combs, M.R., Grossman, B.J., Hillyer, C.D. 2011. Technical Manual of the <u>AABB</u>, 17th ed. AABB Publishing, Bethesda, Maryland.
 Standards for Blood Banks and Transfusion Services, 2012. AABB, 28th ed. AABB
- Publishing, Bethesda, Maryland.

8. **REVISION HISTORY**

| Version | Date | Reason for Revision | Revised By | Approved By |
|---------|---------|--|---------------|----------------|
| | | Supersedes SGAH.B13.001, SGAH B406.01 | | |
| 000 | 5.16.12 | Section 5: Updated wording of procedural steps 1, 2, 5, and 9 for clarity. | SCodina | NCacciabeve |
| 001 | 5.9.13 | Section 5: Added ISBT-128 Information Section 9: Added appendix A | SCodina | NCacciabeve |
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9. ADDENDA AND APPENDICES

Appendix A: ISBT-128 Product Codes

Appendix A ISBT-128 Product Codes

| Original Product Code | Component Prep Function | Final Product Code |
|-----------------------|-------------------------|--------------------|
| E3046 | CE3046 | E3047 |
| E3056 | CE3056 | E3049 |
| E3057 | CE3057 | E3050 |
| E3058 | CE3058 | E3051 |
| E3077 | CE3077 | E3078 |
| E3087 | CE3087 | E3080 |
| E3088 | CE3088 | E3081 |
| E3089 | CE3089 | E3082 |
| E4649 | CE4649 | E3050 |
| E4650 | CE4650 | E3051 |