TRAINING UPDATE

Lab Location:	SGMC andn WOMC	**Date Implemented:**	8/22/2024
Department:	Blood Bank	**Due Date:**	9/5/2024

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

- Component Selection to Reduce the Risk of Transfusion Associated CMV (Cytomegalovirus) Disease
- Red Blood Cell Aliquot Preparation (SGMC)
- Reconstituted Whole Blood Preparation for Neonatal Exchange Transfusion (SGMC)
- Intrauterine Transfusion (IUT) (SGMC)
- Neonatal Exchange Transfusion (WOMC)

Description of change(s):

CMV-seronegative blood products are no longer required for neonates. This was approved by the AHC Transfusion Committee, Neonatal Committees, and Pediatric Committees.

Leukocyte-reduced blood products are considered CMV-safe. CMV lives inside the white blood cells. White blood cells are removed from the donor product during the leukocyte-reduction procedure. CMV is effectively removed when the white blood cells are removed.

A provider can order CMV-seronegative blood products for a neonate if needed. The process will work the same as a CMV request for an adult. However, we do not order CMV testing on neonates and the CMV marker will automatically be removed when the baby is 120 days old.

AHC.BB03 Component Selection to Reduce the Risk of Transfusion Associated CMV (Cytomegalovirus) Disease

Copy of version 6.0 (approved and current)

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Organization Adventist HealthCare

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Approval	Lab Director	8/21/2024	6.0	 Nicolas Cacciabeve	
Approval	BB approval	8/21/2024	6.0	Stephanie Codina	
Periodic review	Medical Director	10/3/2023	5.0	 Nicolas Cacciabeve	
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Approval	QA approval	9/15/2021	5.0	Leslie Barrett	
Periodic review	Medical Director	4/11/2021	4.0	Nicolas Cacciabeve	
Periodic review	BB	4/8/2021	4.0	Stephanie Codina	
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Updated prefix 9/20/21

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
6.0	Approved and Current	Major revision	8/21/2024	8/21/2024	Indefinite

5.0	Retired	Major revision	8/20/2021	9/20/2021	8/21/2024
4.0	Retired	First version in Document Control	6/25/2019	12/12/2016	9/20/2021

Non-Technical SOP

Title	**Component Selection to Reduce the Risk of Transfusion Associated CMV (Cytomegalovirus) Disease**	
Prepared by	Stephanie Codina	Date: 2/14/2010
Owner	Stephanie Codina	Date: 2/14/2010

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
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TABLE OF CONTENTS

1. PURPOSE

Transfusion of cellular blood products from donors who have been exposed to the cytomegalovirus (CMV) may be capable of transmitting CMV. Transmission rates are dependent upon the status of the recipient's immune system. CMV rarely causes problems in immunocompetent individuals but can be fatal in immunocompromised recipients. CMV-seronegative blood products have been tested and found negative for antibodies to CMV and can be issued to patients who require CMV-negative blood products. Leukocyte-reduced blood products can be an alternative to CMV-seronegative blood products in some clinical situations.

2. SCOPE

When a physician requests CMV-negative blood products for a recipient and the recipient meets established hospital criteria, a marker will be placed into the patient's blood bank historical data and **all current and subsequent transfusions must be CMV-seronegative until transfusion of CMV-negative blood products is no longer clinically necessary per treating physician.**

Exceptions:

A. The CMV marker will be automatically removed from a neonate when he/she reaches the age of 4 months (120 days).
B. The CMV marker will be automatically removed from a pregnant recipient as soon as she delivers.

Other than those patients listed above, CMV-seronegative blood products are never indicated for recipients who test positive for antibodies to the CMV virus.

Cellular blood products may be ordered and issued as CMV-seronegative blood products in the following situations:

- When requested by the treating physician for the following reasons:
  - Recipient is a neonate less than 120 days of age
  - Recipients undergoing intrauterine transfusion
  - Recipient has undergone a hematopoeitic progenitor cell transplant (bone marrow, cord blood, or peripheral blood progenitor cells)
  - Recipient will likely undergo a hematopoeitic progenitor cell transplant (bone marrow, cord blood, or peripheral blood progenitor cells)
  - Recipient is CMV-seronegative and has received a solid organ from a CMV-seronegative donor (R=/D=)
  - Recipient is HIV-positive
  - Recipient is currently pregnant
  - Recipient has been designated as an organ donor per Washington Regional Transplant Community protocol
- When requested by the treating physician **and** approved by a pathologist for severe immunosuppression and reasons otherwise not listed

3. RESPONSIBILITY

All Blood Bank employees are required to understand the indications for CMV seronegative products and the steps that must be taken if CMV-seronegative blood products are requested/required.

4. DEFINITIONS

CMV (cytomegalovirus) is a double-stranded DNA virus that resides in leukocytes, specifically monocytes expressing the CD13 marker. CMV can be transmitted via transfusion of cellular blood products (plasma and cryoprecipitate products do not need to be tested for CMV antibodies).

Cellular blood products = Red blood cells, leukocytes, and platelets.

5. PROCEDURE

Step	Action
1	When CMV-seronegative blood products are ordered for the first time, we must determine the CMV status of the recipient. Note: CMV testing is not required for neonates under the age of 120 days,

Step	Action
	patients undergoing intrauterine transfusion, and patients who have been identified as organ donors. Note: Blood bank will issue CMV-seronegative blood products while CMV antibody testing is pending. A. Review the patient's laboratory results using Sunquest function Laboratory Inquiry. B. Search for CMV antibody test results (note all send-out tests begin with an X). a. If the CMV antibody is negative, the patient is a candidate for CMV-seronegative blood products. Proceed to step 3 and add the CMV marker. b. If the CMV antibody is positive, the patient does not require CMV-seronegative blood products. i. Notify the ordering provider that CMV-seronegative blood products will not be issued based on patient's test results. ii. Place a comment in the patient's blood bank history that CMV-seronegative blood products were ordered by Dr. *X* but are not indicated because patient tested positive for CMV antibodies on *date*. c. If the patient does not have CMV antibody results, i. Order a CMV IgG antibody test on the patient. ii. Notify the ordering provider that blood bank will automatically stop giving CMV-seronegative blood products if the patient demonstrates antibodies to CMV. iii. Add a comment to the patient's blood bank administrative data file indicating the CMV testing was ordered on date. iv. Document the CMV order in the communication log and check for return of test results. Follow steps a and b above based on the testing results. CMV antibody testing will be repeated every 2 years.
2	Enter the CMVN attribute into the LIS system with a comment per procedure, "Entering Special Transfusion Attributes into the LIS." The CMVN attribute should be automatically removed from the patient's blood bank administrative data file in the following situations. A. When a neonate who had been receiving CMV-seronegative blood products reaches an age of 4 months (120 days). B. When a pregnant woman who was receiving CMV-seronegative blood products during pregnancy delivers or is no longer pregnant. C. When the recipient tests positive for CMV antibodies.

Step	Action
3	CMV-seronegative blood products may be difficult to obtain in situations where the patient has other special transfusion needs (Antigen-negative blood products, HLA-matched platelets, etc). **When CMV-seronegative blood products are not available:** A. Notify the nurse or physician treating the patient in a timely manner. a. Ask the physician if leukocyte-reduced blood products can be substituted for CMV-seronegative blood products. i. If the physician does not want to substitute products, notify the Blood Bank Medical Director or Clinical Pathologist on-call. ii. If the physician approves substitution with leukocyte-reduced blood products, ascertain how long the substitution is valid (one transfusion, one week, one admission, etc). iii. Document the substitution in patient's historical blood bank data file. Note: Not all techs have access to the patient's BAD file. Notify the blood bank supervisor or administrator on-call for guidance if needed. a) Access Sunquest function "Blood Bank Administrative Data Entry." b) At the "Lookup by" prompt, click on the dropdown menu and select "Patient ID." c) At the "Value" prompt, type in the patient's medical record number and click the "Search" button. d) Press the "Tab" key until your cursor is in the "Comment" field. e) Type a semicolon ";" and free text a comment in indicating which physician approved substitution with leukoreduced blood products and how long the substitution is good for. f) Press the "Save" button. B. Document the notification in the Blood Bank Communication Log.
4	Allocate and crossmatch the blood product to the patient per procedure, "Crossmatch."

6. RELATED DOCUMENTS

SOP: Entering Special Transfusion Attributes into the LIS

7. REFERENCES

1. Technical Manual of the AABB, current ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, current ed. AABB Publishing, Bethesda, Maryland.
3. Circular of information for the use of human blood and blood components. Prepared by AABB, the American Red Cross, America's Blood Centers, and the Armed Services Blood Program. Bethesda, MD: AABB.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	2/14/2010	Updated owner Sections 1 & 2: simplified content Section 5: added patient testing for CMV status and LIS documentation Section 7: updated to current	S. Codina	N. Cacciabeve
001	6/15/2012	Section 2: Updated scope and indications for CMV-seronegative blood products. Section 4: Added definitions. Section 5: Updated some wording in procedure for clarification.	S. Codina	N. Cacciabeve
002	1.27.2015	Section 2: Added that WRTC organ donors will automatically receive CMV-negative blood products. Section 5: Added that CMV antibody testing is repeated every 2 years per hospital policy. Footer: version # leading zeros dropped due to new EDCS in use as of 10/7/13	S. Codina	N. Cacciabeve
3	12.2.2016	Header: Added WAH	L. Barrett	N. Cacciabeve
4	8.20.21	Header: Changed WAH to WOMC, added FWMC Section 2: Moved organ transplant from automatic to physician ordered Section 7: Updated references Footer: Updated prefix to AHC	LBarrett	NCacciabeve
5	8.21.24	Removed the requirement to give neonates CMV-seronegative blood products and made this an option the provider can order; Change Washington Regional Transplant Community to Infinite Legacy	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

A. Indications for the Use of CMV-Seronegative Blood Products

Appendix A
Indications for the use of CMV-Seronegative Blood products (Hospital Policy)

In most situations, there is no benefit to giving CMV-seronegative blood products to patients who have been previously exposed to CMV as evidenced by positive CMV antibody levels. Testing for IgG CMV antibodies is required at the time CMV-seronegative blood products are ordered and every 2 years for subsequent transfusions. Except those in category I below, blood bank will automatically remove the CMV requirement for any patient who demonstrates antibodies to CMV.

Category I
Indications for CMV-seronegative blood products regardless of CMV status:

1. All neonates under the age of 4 months.
2. All patients undergoing intrauterine transfusion.
3. Patients who have been identified as organ donors per the Infinite Legacy protocol.

Category II
Indications for CMV-seronegative blood products in CMV-negative recipients:

4. Recipients of allogeneic hematopoietic progenitor cell transplant (bone marrow, cord blood, peripheral blood progenitor cells).
5. Patients who will likely undergo allogeneic hematopoietic progenitor cell transplant in the future.
6. Solid organ transplant recipients who received CMV-negative organs.
7. HIV-positive patients.
8. Patients who are currently pregnant. Blood bank will remove the CMV marker as soon as the patient delivers.
9. Severely immunosuppressed patients after consultation with the on-call pathologist. Contact the blood bank to reach the on-call pathologist.

CMV-seronegative blood products may be requested for reasons other than those listed after consultation with the on-call pathologist. Contact the blood bank to reach the on-call pathologist.

SGAH.BB92 Red Blood Cell Aliquot Preparation (SGMC only)

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Approval	BB approval	11/18/2021	5.0	Stephanie Codina	
Approval	QA approval	11/18/2021	5.0	Leslie Barrett (104977)	
Periodic review	Medical Director	11/11/2019	4.0	Nicolas Cacciabeve	
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4.0	Retired	First version in Document Control	6/28/2019	10/16/2017	11/18/2021

Linked Documents

- AG.F01 Product Modification Log, SGMC Blood Bank

Non-Technical SOP

Title	**Red Blood Cell Aliquot Preparation**	
Prepared by	Stephanie Codina	Date: 3/27/2011
Owner	Stephanie Codina	Date: 3/27/2011

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
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TABLE OF CONTENTS

1. PURPOSE

To describe the procedure for making small-volume red blood cell aliquots. This procedure allows small amounts of a red blood cell unit to be transfused over the lifespan of the original blood product. This process limits donor exposures and decreases donor-related risks in the recipient while minimizing overall blood wastage.

2. SCOPE

This procedure applies to small-volume red blood cell transfusions requested for neonates and small children as well as "split" units intended for adults at risk of volume overload. SGMC staff members perform all RBC aliquot procedures for WOMC and SGMC.

3. RESPONSIBILITY

All blood bank staff members must be trained and competent in RBC aliquot preparation to ensure the purity, potency, and safety of the aliquoted red blood cell product.

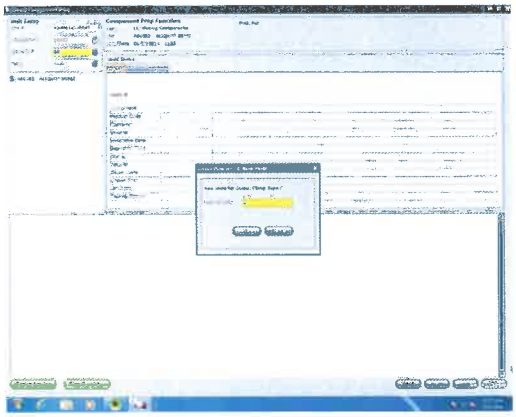
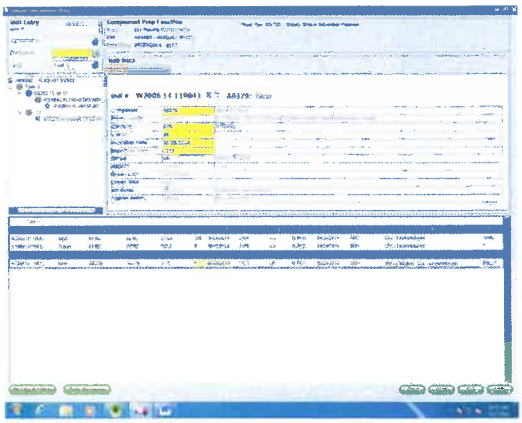
4. DEFINITIONS

N/A

5. PROCEDURE

Step	Action
1	The patient care area will order red cell aliquots using test "TRCNEO." Review the order, special instructions, and volume. Note: We also accept a TRRC order that has an indication to split a red cell unit for an adult in the comment section.
2	Obtain the supplies necessary to aliquot a red cell: A. An aliquot container a. For aliquots <20 mL, use the set with the 30cc syringe. b. For aliquots <50mL, use the set with the 55cc syringe. c. For aliquots >50mL, use a transfer pack **or** two syringes. B. Sterile welding device C. Heat sealer D. Scale E. Hemostats
3	Perform daily QC of the scale if needed.
4	Select a red blood cell that meets the recipient's transfusion specifications. A. Red cells are <u>not</u> routinely crossmatched for infants <4 months of age. B. When the mother of an infant has clinically-significant antibodies (including passive anti-D): a. Antigen-negative units are required. Refer to procedure, "Antigen Typing." b. Both IS and AHG crossmatch are performed. Refer to procedure, "Crossmatch." C. Perform both an IS and AHG crossmatch if mom's history is unknown **and** the baby's antibody screen is positive. D. Refer to procedure, "Neonatal Type and Screen and Crossmatch" for additional instruction. For neonatal transfusions, the following transfusion requirements should be met: A. Group O red cells, Rh-negative are preferred, but Rh-positive may be used for Rh-positive recipients B. CPDA-1 or AS-3 anticoagulant C. Leukocyte reduced D. Hemoglobin S negative E. Irradiated *after* aliquot to reduce potassium leakage F. Negative for antigens present in the baby's or mom's plasma
5	Tighten all connections. The hub connection nearest the syringe has disconnected on rare occasions. **Use aseptic technique for this procedure!**

Step	Action
6	Document the following on the "Product Modification Log" A. Tech identification B. Date of modification C. Unit number D. E code of original and new units (or A code if applicable) E. Lot number of bag or syringe and expiration date of syringe F. Wafer lot number
7	Gently mix the primary bag to resuspend the red cells.
8	Connect the filter-syringe set or transfer bag (whichever is used) to the primary red cell per procedure, "Sterile Tubing Welder."
9	If a transfer bag is used, tare the scale using an empty 150 mL transfer bag.
10	Slowly draw the required amount of blood into the syringe or allow the required amount of blood to flow into the transfer bag via gravity. Include an extra 10 mL of red cells to compensate for the volume that will be lost in the tubing. DO NOT push free air from the syringe back onto the parent unit.
11	Clamp the line when an appropriate amount of blood has been transferred. Seal the line using a tube sealer at least twice. **Do not separate the aliquot from the parent unit at this time.** A. Always ensure the hemostat is clamped between the parent unit and the location in which the tubing will be sealed. B. This will protect the sterility of the unit should the heat seal fail. C. Prepare at least one segment from the line if the product requires crossmatch.
12	Access Sunquest function, Blood Component Preparation. Note: DO NOT branch to blood component preparation (BCP) from blood order processing (BOP).
13	At the "Value" prompt, type the aliquot function that corresponds to the red cells to be aliquotted then press the "Tab" key. The aliquot function is A + the E code of the red cell product. Refer to appendix A for additional information.
14	Press the tab key to default the current date and time as the aliquot time. Enter the date and time on which the aliquot was prepared if prepared at an earlier time (such as during computer downtime).
15	Click the "continue" button.
16	A second "Blood Component Prep" screen will appear. A. At the "Unit #" prompt, scan the unit number DIN of the parent red cell to be aliquoted. B. At the "Component" prompt, scan the product code of the parent unit to be aliquoted. This will autofill both the product code and division fields.

Step	Action
17	A pop-up screen will appear asking the user to indicate the number of units that will be prepared (ie the number of aliquots being prepared at one time). A. Enter 1 in the field. B. Click the "OK" button. 
18	On the next screen, click on the yellow circle containing the N (for new product)." Enter the volume of the red cell aliquot being prepared, then press the "Tab" key. 
19	Verify the new expiration dates/times. Document the new expiration date and time on the log. A. The expiration date of the parent unit will not change if a closed system is used. B. The expiration date of the parent unit will change to 24 hours from the time of aliquot if an open system is used (ie the sterile connection failed). If an open system is used, the output blood product codes in appendix A do not apply. See a supervisor for guidance. C. The expiration date of the aliquot will always be 24 hours from the time of preparation, regardless of whether an open or closed system is used.
20	Click the "Save" button.

Step	Action
21	A "Preview Output / New Units" screen will appear. Review the information to ensure accuracy, then click on the "finish" button to generate new labels for the parent and aliquotted products. A. The first time an aliquot is prepared, the system will convert the parent unit to division "A0" and the aliquot to division "B0." B. All subsequent divisions will assign a division code to the aliquot using the division labeling convention of "Aa, Ab, Ac, Ad…….Az."
22	Adhere the new labels to BOTH the parent unit and the aliquot. **Ensure you adhere the "AO" label to the parent unit.**
23	After labeling, disconnect the aliquot from the parent unit and discard the filter. Use the extra segment for crossmatching, if indicated.
24	If the original product is an apheresis red cell, calculate the amount of anticoagulant in the aliquot and parent red cell products and document in the appropriate space on the blood product label. Each mL of blood contains approximately 0.14 mL of anticoagulant.
25	Document the following on the "Blood Product Modification Log." A. Division number new product B. Documentation of the weld inspection
26	Perform the blood label check for BOTH units in Sunquest per procedure.
27	Irradiate the aliquot per procedure. Do not perform the blood component preparation functions for irradiation as the aliquot function automatically performs these steps. Note: The output blood product automatically converts to an irradiated product E code. You MUST either irradiate the unit or change the E code if you are splitting a unit for an adult patient.
28	Allocate and/or crossmatch the red cell aliquot per procedure.
29	Return the parent product and the aliquot to the appropriate shelves of the refrigerator. Aliquots should be transfused as soon as possible after preparation.

6. RELATED DOCUMENTS

SOP: Antigen Typing
SOP: Crossmatch
SOP: Neonatal Type and Screen and Crossmatch
Form: Product Modification Log (AG.F01)
SOP: Sterile Tubing Welder
SOP: Scale Quality Control
SOP: Blood Label Check
SOP: Blood Component Irradiation

7. REFERENCES

1. Technical Manual of the AABB, current ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, current ed. AABB Publishing, Bethesda, Maryland.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SHB.010.000, SGAH.B404.02		
000	5.8.13	Section 5: Added ISBT-128 Information Section 9: Added appendix B	Scodina	Ncacciabeve
001	5.27.14	Section 5: Removed references to codabar-labeled units. Updated LIS instructions to include the Sunquest v6.4 upgrade. Moved appendix for blood component preparation in the LIS to the procedure. Section 9: Re-numbered appendix Footer: version # leading zeros dropped due to new EDCS in use as of 10/7/13.	Scodina	Ncacciabeve
2	6.1.16	Section 5: Changed dead volume for tubing from 5mL to 10mL due to hospital tubing change. Added statement about irradiation of units that are split for adults. Section 7: Updated references	Scodina	Ncacciabeve
3	9.15.17	Section 5: Added instructions to prepare an extra segment when crossmatch is indicated. Updated volume for syringe due to free air. Stated free air from syringe is not pushed into parent unit.	SCodina	NCacciabeve
4	11.18.21	Section 5: Updated syringe from 60cc to 55cc per manufacturer's change. Section 7: Updated references.	SCodina	NCacciabeve
5	8.21.24	Removed requirement to give neonates CMV-seronegative red blood cells	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

Appendix A: Red Blood Cell Aliquot Blood Component Prep Functions

Appendix A
Red Cell Aliquot Blood Component Prep Functions

Red Blood Cell Aliquot Products

Original Product Code	Component Prep Function	Final Product
E0226	AE0226	A0224
E0382	AE0382	A0379
E0678	AE0678	A0661
E0685	AE0685	A0668
E0686	AE0686	A0669
E4543	AE4543	A4538
E4544	AE4544	A4539
E4545	AE4545	A4540

SGAH.BB877 Reconstituted Whole Blood Preparation for Neonatal Exchange Transfusion (SGMC only)

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Periodic review	Medical Director	6/28/2021	1.0	Nicolas Cacciabeve	
Periodic review	BB	6/24/2021	1.0	Stephanie Codina	
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1.0	Retired	First version in Document Control	6/28/2019	8/17/2015	4/12/2024

Linked Documents

- AG.F288 Reconstituted Whole Blood Worksheet

Non-Technical SOP

Title	**Reconstituted Whole Blood Preparation for Neonatal Exchange Transfusion**
Prepared by	Stephanie Codina Date: 05.29.2014
Owner	Stephanie Codina Date: 05.29.2014

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
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1. PURPOSE

Neonatal exchange transfusion is the treatment of choice for Hemolytic Disease of the Newborn (HDN), hyperbilirubinemia, disseminated intravascular coagulation (DIC), and occasionally the elimination of toxins, drugs, and chemicals in neonates. The procedure consists of replacing two whole blood volumes and has several desired effects. Removal of the infant's blood reduces antibody coated red cells, unconjugated bilirubin, and the number of unbound antibody molecules available to bind newly-formed antigen-positive red blood cells. Reconstituted whole blood is used for this procedure. The red cells used for replacement are compatible with the infant and/or maternal specimen and provide increased oxygen-carrying capacity. The plasma restores albumin and coagulation factors.

2. SCOPE

This procedure applies to the preparation of reconstituted whole blood for any neonate who requires an exchange transfusion.

3. RESPONSIBILITY

All blood bank staff members must understand and adhere to this procedure for the preparation of reconstituted whole blood for a neonatal exchange procedure.

4. DEFINITIONS

Neonate: An infant <4 months of age.

5. PROCEDURE

This procedure must be carried out in steps to ensure proper preparation in the LIS.

A. Select a red cell unit.
B. Select a plasma unit.
C. Thaw the plasma unit.
D. Aliquot the plasma unit.
E. Combine the red cell and plasma together.
F. Irradiate the whole blood unit.

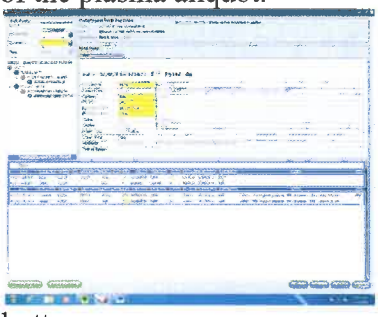
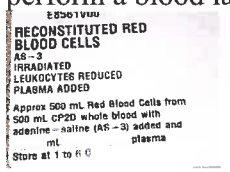
Step	Action
1	The patient care area will order reconstituted whole blood using the order, "TWBNEO." Blood bank staff members will need the following information to process the order. A. Infant's name and medical record number (Note: If blood products for an exchange transfusion are requested before an infant has been delivered, crossmatch the blood product to mom's specimen using downtime procedure. Prepare the product in the LIS and allocate after the baby has been assigned an MRN). B. Mother's name and medical record number, if available. Often the baby is transferred to us from another hospital. C. Date and time of exchange procedure D. Volume of whole blood (this should be 2 times the infant blood volume) E. Specimens for T&S on the mother (if the baby was delivered at SGMC) and TSNEO on the infant (if not already available)
2	Document the following information on the Reconstituted Whole Blood Worksheet. A. Infant's full name and medical record number. B. Mom's full name and medical record number, if available. C. Date and time of expected transfusion (write "STAT" if blood is needed as soon as possible). D. Volume of whole blood requested (A) on worksheet.

Step	Action
3	Order blood products from the supplier (if needed) and **emphasize delivery time**. Blood products should meet the following criteria: A. Group O (Rh-negative if the recipient is Rh-negative) B. Fresh red cells (<7 days old) to avoid high levels of potassium and to maximize red cell survival C. CPDA-1 or AS-3 red cells D. Irradiated (note: irradiation should be performed after reconstitution to ensure both red cells and plasma are irradiated per ICCBBA description) E. Sickle-negative F. Negative for any antigens that correspond to clinically-significant maternal antibodies. G. AHG crossmatch compatible with the mother's plasma (preferred) or the baby's plasma (alternate).
4	Crossmatch the unit to the mother's plasma. If mother's plasma is not available, the unit should be crossmatch compatible with the infant's plasma. **AHG crossmatch is required for provision of reconstituted whole blood when a neonate is hemolyzing for any reason. Mom may demonstrate an antibody to a low frequency antigen that may not show in an antibody screen.** Crossmatch may be performed on downtime prior to reconstituting the blood product.
5	Obtain the supplies necessary to reconstitute the blood product. A. Sterile welding device B. 150 mL transfer bag C. Heat sealer D. Test tubes E. Scale F. Hemostats
6	Perform daily QC of the scale if needed.

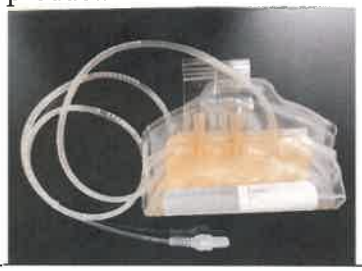
Step	Action
7	Obtain a pre-hematocrit of the original unit: A. Mix the red cell unit manually by gently rotating it back-and-forth. B. Sterile dock a 150 ml transfer bag to the unit or use an attached satellite bag if available. C. Allow small sample of blood to flow into the tubing of the empty 150 ml sterile bag. D. Apply hemostat on the tubing toward the original unit once red cells fill up the tubing. E. Seal the tubing of the original unit first using the heat sealer leaving enough tubing for the next component prep. F. Make 3 or more segments, 2-3 inches long, label each segment with the unit number of donor identification number (DIN). Use of the labels found on the back of the original red cell unit is preferred. It is not necessary to label the aliquot bag since the labeled segments are used for unit hematocrit testing. G. Separate the segments from the original blood product unit. H. Pierce the end of 1-2 segments and drip the blood into a clean test tube labeled with the unit number. I. Deliver the sample to hematology and request STAT hematocrit testing. Instruct the hematology tech to test the specimen in duplicate and average the results. J. Convert the hematocrit to a decimal (Ex. 75% = 0.75).
8	Document the unit's hematocrit (B) on the worksheet.
9	Select and thaw a unit of plasma per procedure. A. Group AB plasma is preferred. B. Plasma from whole blood donation (non-apheresis) plasma is also preferred. Selection of apheresis plasma will require calculation of the volume of anticoagulant solution. C. If group AB plasma is not available, select a unit of plasma that is compatible with the infant and mother's types. D. Plasma must be thawed fresh for this procedure (do not use a unit of thawed plasma on the shelf).
10	Approximate the volume of red cells in the primary red cell container. A. Weigh the bag of red cells. B. Subtract 100g (the approximate weight of the bag, anticoagulant, and segments). C. Document the red cell volume (C) on the worksheet.

Step	Action
11	Calculate the amount of thawed plasma to be added to the packed red cell unit for reconstitution per the following formula. Use the worksheet to aid in this calculation. **Desired volume of whole blood unit = $\frac{\text{(Hct of original red cell) x (Volume of original red cell in mL)}}{0.53}$** **Volume of plasma to add = (Volume of whole blood unit) – (Volume of original red cell)** Key: Original red cell = the packed red blood cell that was pulled out of inventory Whole blood unit = reconstituted whole blood unit; the red cell with added plasma **Example:** You have 200mL of packed red blood cells with a hematocrit of 75%. Volume of whole blood = (0.75 x 200) ÷ 0.53 = 283 mL Volume of plasma to add = 283 mL – 200 mL = 83 mL Add 83 mL of plasma to the red cell unit to obtain whole blood with a hematocrit of ~53%.
12	Prepare a plasma aliquot per procedure. A. The volume of the aliquot will be the "volume of plasma to add" as calculated in the step above. B. The plasma aliquot must be prepared per procedure. a. Prepare the plasma aliquot. b. Perform the blood component preparation function to create the aliquot in Sunquest. c. Perform the blood label check in Sunquest. C. Document preparation of the aliquot on the Product Modification Log.
13	Add the plasma aliquot to the red cell unit. A. Use the sterile connecting device to connect the thawed plasma aliquot to the red cell unit. B. Document adding the plasma on the Product Modification Log. C. Transfer the contents of the plasma aliquot to the red cell unit. D. Weigh the bag. E. Subtract 100g (the approximate weight of the bag, anticoagulant, and segments) to obtain the new volume of the reconstituted whole blood unit. F. Document the volume (F) on the worksheet.

Step	Action
14	Prepare segments on the new, reconstituted product. A. Gently knead the bag to mix the contents. B. Allow the tubing to refill with the well-mixed reconstituted whole blood. C. Strip the blood in the remaining tubing three times back into the cell bag, mixing well each time. D. Heat seal the line beginning at the end of the tubing and moving towards the bag forming at least 4 segments. Place a double-seal next to the bag.
15	Obtain the hematocrit of the new, reconstituted product. A. Label a clean test tube with the unit number. B. Separate 1-2 segments from the original blood product unit. C. Pierce the segments and drain the contents into the clean, labeled test tube. D. Deliver the sample to hematology and request STAT hematocrit testing. E. Instruct the hematology tech to test the specimen in duplicate and average the results. F. Ensure the hematocrit is within 5% of the desired hematocrit. Notify a supervisor if discrepancies exist.
16	Reconstitute the whole blood product in the LIS. A. Access Sunquest function, "Blood Component Preparation." B. At the "Value" prompt, type "R" plus the E code of the original red cell unit then press the "tab" key. E codes that can be used are: • E0226 • E0382 • E0678 • E0685 • E0686 • E4543 • E4544 • E4545 C. Press the tab key to default the current date and time as the reconstitution time. Enter the date and time of reconstitution if prepared at an earlier time (such as during a computer downtime). D. Click the "Continue" button.

Step	Action
16 Cont	E. A second 'Blood Component Prep" screen will appear. a. At the "Unit #" prompt, scan the unit number of the **plasma** aliquot product. b. At the "Component" prompt, scan the E code of the **plasma** aliquot. This will autofill both the component and division fields. c. The cursor will return to the "Unit #" prompt. Scan the unit number of the **packed red blood cell** product to be reconstituted. d. The LIS will prompt, "Pick input component." Select the red cell product and click the "OK" button. e. You will see the QA failure message, "Input unit(s) expire before output unit:" Acknowledge the QA failure. F. Click on the yellow circle that contains the "O." f. Enter the volume of the whole blood unit. The volume will not necessarily equal the combined volumes of the red cell unit and plasma aliquot as defined in the computer. g. Enter the expiration date of the reconstituted product. The reconstituted product will expire 24 hours from the time the plasma was thawed. The expiration date/time of the reconstituted whole blood unit should equal the expiration date/time of the plasma aliquot.  G. Click the "Save" button. H. A "Preview Output / New Units" screen will appear. Review the information to ensure accuracy, then click on the "finish" button to generate a new label for the reconstituted product.
17	The new label will print with 3 blank spaces printed on it. A. Write the volume of plasma added in the first space. B. Write the plasma anticoagulant in the second space. C. Write the ABO and Rh of the plasma in the third space. D. Adhere the new label directly over the label of the red cell unit and perform a blood label check in Sunquest per procedure. 

Step	Action
18	Irradiated the red cell per procedure. A. Physically irradiate the reconstituted whole blood product. B. Document the irradiation on the irradiation log. C. Perform the blood label check in Sunquest. D. The irradiation function is built into the LIS reconstitution; LIS update is NOT required.
19	Document the post-hematocrit and volume in the LIS. A. Access function "Blood Product Testing." B. At the "Unit Number" prompt, scan the unit number of the original unit. C. At the "Component" prompt, scan the E code of the reconstituted unit. This will autofill both the Component and Division # fields. D. Click on the "Add" button. E. Click on the "Continue" button. F. In the "Test" column, type ";UHCT." G. The prompt, "Confirm adding test UHCT" will appear. Click on the "Yes" button. H. In the result column, type a semicolon followed by the unit's hematocrit. (Ex = ;0.55) then press the "tab" key. I. Click the "Save" button.
20	Allocate the unit and result the crossmatch per procedure.
21	Notify the patient care area when the product is available for issue. Instruct the patient care area that the unit has a short expiration and should be transfused as soon as possible. If the volume of the reconstituted product is: A. GREATER than the volume requested. Issue the entire product. The patient care area will pull off the desired volume. B. LESS THAN the volume requested. Notify the patient care area that you will prepare an additional reconstituted unit if needed.
22	Store the product in the refrigerator (1-6°C) until issue or expiration.

Step	Action
23	Prepare a waste bag for the nursing unit if requested. A. Obtain one SmartSite Extension Set from NICU and one transfer bag (preferably 600mL, but 300 mL is acceptable).  SmartSite Extension Set B. Place the tubing in the sterile docking device so that the screw luer from the SmartSite extensionSset will attach to the bag, and the spike will be removed. The luer and the spike need to be on the same side when using the sterile docker.  C. Sterile dock the screw luer onto the bag per procedure. This will be used for waste only and does not need to be documented on the product modification log. D. Provide the waste bag to the floor with the reconstituted whole blood product. 

6. RELATED DOCUMENTS

Form: Reconstituted Whole Blood Worksheet (AG.F288)
Form: Product Modification Log (AG.F01)
SOP: Procurement of Blood Products and Desired Inventory Levels
SOP: Scale Quality Control
SOP: Plasma for Transfusion
SOP: Blood Component Irradiation
SOP: Plasma Aliquot Preparation
SOP: Blood Label Check
SOP: Crossmatch
SOP: Sterile Tubing Welder

7. REFERENCES

a. Technical Manual of the AABB, current ed. AABB Publishing, Bethesda, Maryland.
b. Standards for Blood Banks and Transfusion Services. AABB, current ed. AABB Publishing, Bethesda, Maryland.
c. Circular of Information for the Use of Human Blood and Blood Components Prepared by: AABB, the American Red Cross, America's Blood Center and the Armed Services Blood Program. Item 223001. December 2021. Bethesda, MD.
d. Code of Federal regulations, 21 CFR, Parts 200 and 600. Washington DC: US Government Printing Office, Current edition.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
0	7.27.2015	Section 5: Edited order of preparation; irradiation is now last to comply with ICCBBA requirements. Removed requirement for MD to specimen final Hct; neonatologists agreed on 50-55%. Added AS-3 red cells to SOP. Added instructions for preparing waste bag. Section 7: Updated references.	SCodina	NCacciabeve
1	4.10.2024	Updated E codes that can be used for RWB. Updated procedure for sterile docking a luer lock to a bag for waste. Update references. Updated SOP format to current standards.	SCodina	NCacciabeve
2	8.21.24	Removed the requirement for CMV-seronegative red cells	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

N/A

SGAH.BB106 Intrauterine Transfusion (IUT) SGMC only

Copy of version 2.0 (approved and current)

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Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	8/21/2024	2.0	 Nicolas Cacciabeve	
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Periodic review	Medical Director	7/17/2023	1.0	 Nicolas Cacciabeve	
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Periodic review Captured outside MediaLab	Designated Reviewer	6/5/2017	1.0	Nicolas Cacciabeve	Recorded on 6/28/2019 by Leslie Barrett (104977) when document added to MediaLab
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Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	8/21/2024	8/21/2024	Indefinite
1.0	Retired	First version in Document Control	6/28/2019	7/31/2013	8/21/2024

Non-Technical SOP

Title	**Intrauterine Transfusion (IUT)**	
Prepared by	Stephanie Codina	Date: 4/13/2011
Owner	Stephanie Codina	Date: 4/13/2011

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

TABLE OF CONTENTS

1. PURPOSE

Fetal anemia can become severe and life-threatening in severe cases of hemolytic disease of the fetus or newborn (HDFN). In these situations, intrauterine transfusion (IUT) with red cells that lack the antigen that corresponds to the mother's antibodies is used to sustain the fetus until delivery. This procedure describes the process for preparing blood products for IUT.

2. SCOPE

This procedure applies to any red cell product that is requested for intrauterine transfusion (IUT).

3. RESPONSIBILITY

All blood bank staff members must understand the transfusion requirements and blood product preparation steps necessary to provide blood for an IUT.

4. DEFINITIONS

N/A

5. PROCEDURE

Step	Action
1	The patient care area should notify blood bank at least 2 days in advance of an IUT procedure. Advance notification may not be possible in emergency situations.
2	The blood bank technologist will obtain the following information at the time of initial notification: A. Mother's name B. Mother's medical record number C. Date and time of procedure D. Mother's type and screen specimen (at least 24 hours in advance) E. Desired volume and hematocrit of red cell product
3	Order the appropriate red blood cell unit from the blood supplier. Carefully coordinate delivery of the washed or deglycerolized red cells to arrive in time for, but not too early for, the scheduled procedure. **Washed and deglycerolized red cells expire 24 hours from the time the washing/deglycerolizing procedure is started.** Red cells should meet the following specifications: A. O-negative RBCs B. Washed or deglycerolized C. Negative for antigens that correspond to maternal clinically-significant antibodies. D. Hemoglobin S-negative (sickle-negative) E. Irradiated (ask the blood supplier to irradiate the washed red cell prior to shipping)

When the red cells arrive,

Step	Action
4	Enter the red cell into inventory per procedure, "Entering Blood Products Into Inventory."
5	Crossmatch the unit to the maternal T&S specimen per procedure, "Crossmatch." A. Both an immediate spin and AHG crossmatch are performed. B. The unit is allocated and crossmatched to the mother's T&S specimen.

Step	Action
6	Obtain a hematocrit on the unit. A. Mix the unit thoroughly by gently rotating back-and-forth. B. Sterile dock a transfer pack to the unit. C. Allow a small sample of the blood to flow into the tubing of the empty bag. D. Apply a metal clip to protect the parent unit and then heat seal the tubing. E. Label a 12 x 75 mm test tube with the unit number. F. Drain the blood from the segment(s) into the clean, labeled test tube. This will be used for hematocrit testing. Deliver the hematocrit specimen to hematology and request that a STAT hematocrit be run in duplicate
7	Average the two hematocrit results and enter the results in the LIS. A. Access Sunquest function "Blood Product Testing." B. Scan or type the unit number in the "Unit #" prompt. C. Scan or type the collecting facility if prompted to do so. D. Select the correct component from the drop-down menu. E. Press the "Tab" button. F. Click on the "Add" button. G. Click on the "Continue" button. H. Click on the first available white box in the "Test" column. I. Type ";UHCT" and press the "Tab" key. J. The message "Confirm adding test: UHCT" will appear. Click on the "Yes" button. K. In the "Result" column, type the semicolon twice ";;" and then type the unit's hematocrit value. L. Click the "Save" button. M. The message "Product test result has been filed for unit ######." N. Click the "OK" button.
8	Store the blood product at refrigerated temperatures (1-6°C) and issue per procedure, "Issuing Blood Components."

6. RELATED DOCUMENTS

SOP: Entering Blood Products Into Inventory
SOP: Crossmatch
SOP: Issuing Blood Components

7. REFERENCES

1. Technical Manual of the AABB, curent ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services. AABB, current ed. AABB Publishing, Bethesda, Maryland.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAH B402.02		
000	9.9.12	Section 5: Updated to request irradiated blood from the blood supplier instead of irradiating at SGAH	SCodina	NCacciabeve
1	8.21.24	Removed requirement for CMV-seronegative red cells	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

Appendix A: Calculating the Volume of Red Cells to be Transfused

Appendix A

Calculating the Volume of Red Cells to be Transfused

Note: Blood bank does not calculate the volume of red cells to be transfused. However, the formula is provided in the event that a provider asks for guidance.

The volume of blood to be transfused can be calculated:

A. Fetoplacental blood volume = ultrasound estimated fetal weight (g) x 0.14 mL/g

B. Difference in hematocrit = Desired Post-transfusion Hct – Pre-transfusion Hct

C. Hematocrit of unit

$$\textbf{Blood Volume to be transfused} = \frac{\textbf{A x B}}{\textbf{C}}$$

Example:

- Estimated fetal weigh from ultrasound = 1000g
- Post-transfusion hct = 40%
- Pre-transfusion hct = 15%
- Hct of unit = 75%

1000 g x 0.14 mL/g = 140 mL fetoplacental blood volume

40 – 15 = 25 difference in hematocrit

(140 mL x 0.25) ÷ 0.75 = **47 mL**