TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	08.03.2015
Department:	Blood Bank	**Due Date:**	08.15.2015

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Reconstituted Whole Blood Preparation for Neonatal Exchange Transfusion

Description of change(s):

1. Per neonatologists,
    a. All neonatal exchanges will be 2 x blood volume
    b. Will be reconstituted to a hct of 50-55%
2. We can use CPDA-1 or AS-3 units
3. Emphasized requirement that AHG XM is required
4. We will no longer irradiate the RBC prior to reconstitution; we have to irradiate the whole blood product, or ICCBBA requires that we label the product "red cells irradiated; plasma not irradiated"
5. Added instructions for providing a waste bag to the NICU (if requested) for the exchange transfusion
6. Form updated to standardized hct

Electronic Document Control System

Quest Diagnostics

Document No.: SGAH.BB877[1]

Title: Reconstituted Whole Blood Preparation for Neonatal Exchange Transfusion

Owner: LESLIE.X.BARRETT LESLIE BARRETT

Status INWORKS

Effective Date: 28-Aug-2015 **Next Review Date:**

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**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

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.

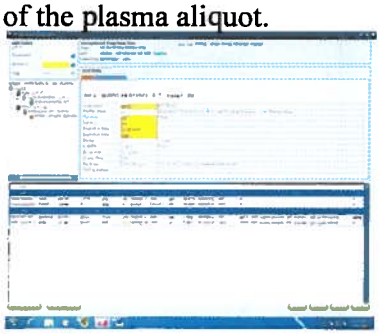
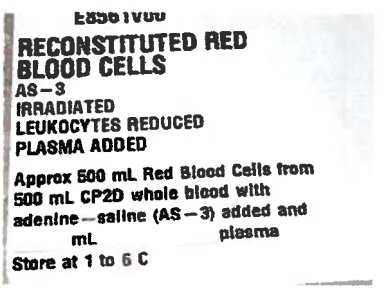
Step	Action
1	The patient care area will order reconstituted whole blood using the order, "TWBNEO." Blood bank staff members will need the following information to process the order. A. Infant's name and medical record number (Note: If blood products for an exchange transfusion are requested before an 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. CMV-seronegative E. Irradiated (note: irradiation should be performed after reconstitution to ensure both red cells and plasma are irradiated per ICCBBA description) F. Sickle-negative G. Negative for any antigens that correspond to clinically-significant maternal antibodies. H. AHG crossmatch compatible with the mother's plasma. If the mother's plasma is not available, the unit should be AHG 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.**
4	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
5	Perform daily QC of the scale if needed.

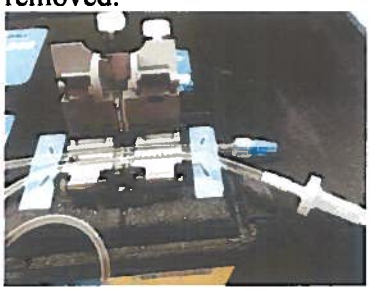
Step	Action
6	Obtain a pre-hematocrit of the original unit: A. Mix the red cell unit manually by gently rotating it back-and-forth. B. Sterile dock a 150 ml transfer bag to the unit or use an attached satellite bag if available. C. Allow small sample of blood to flow into the tubing of the empty 150 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). .
7	Document the unit's hematocrit (B) on the worksheet.
8	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).
9	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
10	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%.
11	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.
12	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 aliquotted plasma 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
13	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.
14	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.
15	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. a. Type RE0226 for CPDA-1 units b. Type RE0382 for AS-3 units 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. 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 (E0226 or E0382) and click the "OK" button. e. You will see the QA failure message, "Input unit(s) expire before output unit:" Acknowledge the QA failure.

Step	Action
15 Cont	F. Click on the yellow circle that contains the "O." a. 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. b. 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.
16	The new label will print with 3 blank spaces printed on it. (Note: the computer will prompt for the following when labels are printed during periods of computer downtime). 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.  RECONSTITUTED RED BLOOD CELLS AS-3 IRRADIATED LEUKOCYTES REDUCED PLASMA ADDED Approx 500 mL Red Blood Cells from 500 mL CP2D whole blood with adenine-saline (AS-3) added and mL plasma Store at 1 to 6 C 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
17	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.
18	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.
19	Allocate the unit and perform an AHG crossmatch per procedure.
20	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.
21	Store the product in the refrigerator (1-6°C) until issue or expiration.

Step	Action
22	Prepare a waste bag for the nursing unit if requested. A. Obtain one component-recipient set (this is the tubing dispensed with platelets) and one transfer bag (preferably 600mL, but 300 mL is acceptable). B. Place the tubing in the sterile docking device so that the screw luer from the component-recipient set will attach to the bag, and the spike will be removed.  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. Fung, MK, Grossman, BJ, Hillyer, CD, and Westhoff, CM. 2014. Technical Manual of the AABB, 18th ed. AABB Publishing, Bethesda, Maryland.
b. Standards for Blood Banks and Transfusion Services, 2014. AABB, 29th 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. 2009. 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

9. ADDENDA AND APPENDICES

N/A

Electronic Document Control System

Quest Diagnostics

Document No.: AG.F.288[2]
Title: Reconstituted Whole Blood Worksheet
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 28-Aug-2015 **Next Review Date:**

Shady Grove Medical Center
Rockville, MD 20850

Reconstituted Whole Blood Worksheet

	Infant's Information	Mom's Information
Name		
Medical Record Number		
ABO/Rh		
Antibody History	N/A	

Product Information

Date/Time of Exchange		☐ **Needed STAT**
Desired Volume		**(A)**

Red Blood Cell Unit Information

Unit Hematocrit Red Cell Product	To convert a percent to decimal, move the decimal place 2 places to the left. Example: 70% =0.70	**(B)**
Unit Volume (mL) Red Cell Product		**(C)**

Calculate the volume of plasma needed for reconstitution:

Step 1: Multiply the red cell unit hematocrit (B) times the red cell unit volume (C)

(B)_____ x (C)_____mL = (D)_____mL

Step 2: Divide the product (D) obtained in step 1 by the desired hematocrit (0.50 to 0.55)

(D)_____mL ÷ 0.53 = (E)_____mL

Step 3: Subtract the red cell unit volume (C) from the quotient (E) obtained in step 2

(E)_____mL – (C)_____mL = [ ] mL ⇨ Volume of plasma to add

Final Hematocrit of Reconstituted Product	To convert a percent to decimal, move the decimal place 2 places to the left. Example: 70% =0.70
Final Volume (mL) of Reconstituted Product	**(F)**

Step 4: Subtract the Final Volume (F) from the Desired Volume (A)

(A)_____mL – (F)_____mL = (G)_____mL

- **If G is a negative number, issue the unit as is.**
- **If G is a positive number, notify the patient care area that the volume is lower than requested and ask if a second unit is needed.**