TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	2.28.2014
Department:	Blood Bank	**Due Date:**	3.15.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Reagent Receipt and Acceptance

Description of change(s):

- The only edits to this procedure were made to Appendix A.
- A section for "Indicator Labels" was added to the LAST page of the procedure.
- We now need to do reagent receipt QC for HemoTempII Indicators AND Rad-Sure Labels.
    - We need to activate a HemoTemp II indicator and apply it to the thermometer bag. The temperature of the HemoTemp II indicator must match the thermometer within 1°C.
    - We must irradiate a Rad-Sure label to ensure the "NOT" becomes obscured.
- Both labels still require label verification and documentation in the label logbook.

Non-Technical SOP

Title	**Reagent Receipt and Acceptance**	
Prepared by	Stephanie Codina	Date: 1.26.2012
Owner	Stephanie Codina	Date: 1.26.2012

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**

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1. PURPOSE

Reagents used for testing, processing, preservation, storage, distribution, transport, and administration of blood products have the potential to affect quality. Reagents must be inspected and tested to ensure they meet the specifications for their intended use prior to be placed into service.

2. SCOPE

This procedure applies to all critical reagents and supplies that are received in blood bank for use.

3. RESPONSIBILITY

All blood bank staff members must understand and adhere to this procedure for receiving and placing into use critical reagents and supplies.

4. DEFINITIONS

N/A

5. PROCEDURE

General Considerations

Step	Action
1	Only reagent and kits licensed by the Food and Drug Administration (FDA) will be used for patient and donor testing.
2	A manual of manufacturer's instructions will be maintained. These directions will be reviewed each time a new lot number of reagent is received. A. New directions placed into the Manufacturer's Instructions binder. B. Outdated instructions will be removed, initialed, and dated and retained for a minimum of 5 years.

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Step	Action
3	Reagents will be stored at the manufacturer's recommended temperature range when not in use. Opened reagents stored at room temperature will have their expiration dates shortened as required per manufacturer's instructions.
4	All reagents poured or stored into a secondary container (such as saline) will be labeled with a laboratory reagent label. Exception: Lot numbers of PBS stored on the Echo will be tracked using the "Phosphate Buffered Solution Tracking Sheet." Prepared reagents may require assignment of an expiration date. A. Elukit Working Wash Solution is good for 6 months after reconstitution if stored at 1-8°C. Working Wash Solution should not be used if turbid. B. Sickledex buffer expires 45 days after reconstitution if stored at 2-10°C. Sediment may appear in the buffer during storage but will not interfere with testing. C. Saline cubes are assigned an expiration date of 30 days after they are opened. D. Saline bottles are cleaned, filled, and labeled weekly and as needed. Each technologist is responsible for changing the saline at his/her station. E. Sickle control vials expire 100 days after opening.
5	Reagents must be dated and initialed when opened.
6	Reagents used for patient testing will be quality controlled prior to being placed into use and at a frequency defined by the Reagent Quality Control procedure (generally each day of use). NEVER use reagents for patient testing if quality control results do not meet acceptable criteria.
7	Outdated reagents are removed from use and discarded with the following exceptions: A. Outdated antibody identification panels are kept up to 3 months past their expiration date provided there is no visible hemolysis. These cells may be utilized for antibody identification in certain instances (such as antibody identification in cases of multiple antibodies, antibodies to high-frequency antigens, antibodies to low-frequency antigens, etc.). B. Outdated A_1 and A_2 cells are maintained for testing of suspected anti-A1 antibodies provided there is not visible hemolysis. C. Rare antisera, other than those of the Rh system, may be used beyond the expiration date if no in-date reagent is available and if positive and negative controls are tested on the day of use and react as expected. D. Expired Capture strips may be stored for instrument maintenance that will not be affected by the reagent expiration date (example = expired strips for Echo residual saline and dispense accuracy tests or manual capture balance strips).

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Step	Action
	E. Expired reagents may be stored for student use. These reagents will be clearly marked "Expired—Do Not Use for Patient Testing" and will be stored away from other reagents.
8	Individual components of reagent kits are not interchanged between lot numbers unless specified by the manufacturer.
9	Reagent quality control performance is reviewed weekly by the group lead and a monthly QC summary is reviewed by the Medical Director.

Supply Receipt

Step	Action
1	Reagents are received and tracked per laboratory procedure, "Supply Ordering, Receiving, and Restocking."
2	Reagents are inspected upon receipt and logged in the "Product Received Log." A. Each reagent is documented on its own sheet. B. Document the date received, quantity received, lot number, and expiration date of each reagent received, and tech initials. C. All reagents received into inventory are documented; including those borrowed from another hospital.
3	Visually inspect each product/reagent for signs of leakage, broken bottles/packaging, hemolysis, improper storage, and deterioration. A. Document the visual inspection in the "Product Received Log" book. a. Document "S" if the visual inspection is satisfactory. b. Document "U" if the visual inspection is unsatisfactory. B. Do not put into service any reagent that fails visual inspection. a. Document disposition in the "Product Received Log" book. b. Complete a PI/Variance form documenting the issue. C. Notify a supervisor if any reagent has questionable reagent quality. Place the supply/reagent on the quarantine shelf until a final decision has been made concerning the reagent disposition.

Step	Action
4	Review the package insert for each reagent received. A. Ensure that the version and revision date of the current package insert match the version and revision date of the new package insert. B. Document the revision date of the package insert in the log. C. If the package insert is different, make a copy of the current and new inserts and forward to a supervisor for review. Note: Ortho Clinical Diagnostics does not include manufacturer's instructions with reagents. Manufacturer's instructions must be obtained from the Ortho Clinical Diagnostics website. Notify a group lead for assistance.
5	If the reagent contains an antigram, place a copy of the antigram in the antigram book. Document that this step has been completed by checking the appropriate column in the Reagent Receipt Log.
6	Complete a Reagent Receipt QC form for new reagents by filling in the following information: A. Name of reagent being quality controlled. Note: Other reagents used for the quality control process are documented on the Daily Reagent QC form and do not need to be added to this form. B. Manufacturer C. Lot number D. Expiration date E. Received date and tech initials F. Quantity received Place the form in the front of the Reagent Receipt Log book.
7	Place a red, circle sticker on <u>each</u> package of reagent received and store the supplies/reagents in the designated location. In addition to the red circle, place a yellow circle on subsequent shipments of any reagent that contains the same lot number. This will help to differentiate different shipments of the same lot of reagent that require reagent receipt QC. Note: It is very helpful to segregate new lot and new shipments of reagent from the current, in-use lots of the same reagent in some fashion. This can be accomplished by placing a rubber-band around packages of different lot numbers of reagent or physically separating reagents (though not always possible given space constraints).

Quality Control

Step	Action
1	**All** reagents must be tested prior to being placed into use. A. This is accomplished by performing quality control of each reagent. B. Every **lot** and **shipment** of reagents is quality controlled. This includes shipments borrowed from another hospital with the same or a different lot number. C. The quality control may be performed at any point between receipt and the time the reagent is placed into use.
2	Obtain the partially-completed Reagent Receipt QC form for new reagents and fill in the following information: A. Testing date B. Tech performing testing
3	For reagents that will be quality controlled manually: A. Complete the testing per appendix A and document the reaction results in the appropriate column(s) on the QC form. B. Determine if the quality control results are acceptable. Document acceptability on the QC form by marking "Y" or "N" in the "Acceptable?" column. For reagents that will be quality controlled on the Echo: A. Perform quality control testing on the Echo. B. Print the QC results and attach them to the Reagent Receipt QC form. C. Document that the QC was performed on the Echo by checking the box on the QC form. D. Note: Do not quality control reagents QC'd on the Echo until they are placed into use. The Echo will not run new reagents without successful QC performance. However, testing does change the expiration date on the reagents.
4	Place a green, circle sticker on each box of reagent that will be placed into use following acceptable performance of quality control testing. Place the green sticker directly on top of the red sticker that was placed upon receipt.
5	When the reagent is placed into use, document the in use date on the QC form.
6	Do not put into use any reagent that fails quality control testing. A. Document disposition in the "Product Received Log" book and on the Reagent Receipt QC form. B. Complete a PI/Variance form documenting the issue. C. Notify a supervisor if any reagent has questionable reagent quality. Place the supply/reagent on the quarantine shelf until a final decision has been made concerning the reagent disposition.

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6. RELATED DOCUMENTS

Form: Reagent Receipt QC (AG.F152)
Form: Product Received Log (AG.F149)
SOP: Supply Ordering, Receiving, and Restocking

7. REFERENCES

None

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH.BB22.000, SGAH.BB25.000		
000	10.16.13	Section 5: Added disclaimer for PBS on Echo. Added expiration for sickle controls. Added reference to new lab policy for supplies. Added instructions to add a yellow dot to same lot reagents received in different shipments. Minor changes to working for clarity. Section 6: Updated forms, add lab policy.	SCodina	NCacciabeve
		Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	LBarrett	
1	2.12.14	Added "Indicator Labels" section to appendix A.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

Appendix A: Quality Control Requirements by Reagent

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Appendix A
Quality Control Requirements by Reagent

Manual Testing Reagents

Reagent	Action
Anti-A, Anti-B, Anti-A,B	1. Label 2 test tubes for the positive and negative controls. 2. Add 1 drop of antisera (anti-A, anti-B, or anti-A,B) to each of the tubes. 3. Add 1 drop of Confidence cell 1 to the positive control tube. 4. Add 1 drop of Confidence cell 2 to the negative control tube. 5. Mix gently. 6. Serofuge for the immediate spin time listed on the serofuge. 7. Read and grade reactions using an agglutination viewer. 8. Immediately record results on the QC form. 9. Expected results: a. Positive = ≥2+ b. Negative = 0 Note: Anti-A and Anti-B may be quality controlled manually or on the Echo.
Anti-D, Series 4	1. Label 2 test tubes for the positive and negative controls. 2. Add 1 drop of anti-D, series 4 to each of the tubes. 3. Add 1 drop of Confidence cell 2 to the positive control tube. 4. Add 1 drop of Confidence cell 1 to the negative control tube. 5. Mix gently. 6. Serofuge for the immediate spin time listed on the serofuge. 7. Read and grade reactions using an agglutination viewer. 8. Immediately record results on the QC form. 9. Incubate the negative control tube for 15 minutes at 36-38°C. 10. Wash a minimum of 3 times with saline. 11. Add 2 drops of anti-IgG. 12. Mix gently. 13. Serofuge for the AHG time listed on the serofuge. 14. Read and grade reaction using an agglutination viewer. 15. Immediately record results on the QC form. 16. Add 1 drop of check cells to a negative reaction. 17. Mix gently. 18. Serofuge for the AHG time listed on the serofuge. 19. Read and grade reaction using an agglutination viewer. 20. Immediately record results on the QC form. 21. Expected Results: a. Positive = ≥2+ b. Negative = 0 at immediate spin and AHG, ≥2+ after addition of check cells Note: Anti-D, series 4 may be quality controlled manually or on the Echo.

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Reagent	Action
A_1 Cells, A_2 Cells, B Cells	1. Label 2 test tubes for the positive and negative controls. 2. Add 1 drop of Confidence antibody to the positive control tube. 3. Add 1 drop of albumin to the negative control tube. 4. Add 1 drop of reagent red cell (A_1, A_2, or B) to each of the tubes. 5. Mix gently. 6. Serofuge for the IS time listed on the serofuge. 7. Read and grade reaction using an agglutination viewer. 8. Immediately record results on the QC form. 9. Expected results: a. Positive = ≥2+ b. Negative = 0 Note: A_1 and B cells may be quality controlled manually or on the Echo.
AHG, polyspecific	1. Label 3 test tubes for controls. a. IgG Pos b. C3 Pos c. Neg 2. Add 2 drops of polyspecific AHG to each of the 3 tubes. 3. Add 1 drop of check cells to the IgG Pos tube. 4. Add 1 drop of complement check cells to the C3 Pos tube. 5. Add 1 drop of B cells to the Neg tube. 6. Mix gently. 7. Serofuge for the immediate spin time listed on the serofuge. 8. Read and grade reaction using an agglutination viewer. 9. Immediately record results on the QC form. 10. Incubate the negative tubes at room temperature for up to 5 minutes. 11. Serofuge for the immediate spin time listed on the serofuge. 12. Read and grade reaction using an agglutination viewer. 13. Immediately record results on the QC form. 14. Expected results: a. Positive (both IgG and C3) = ≥2+ b. Negative = 0
Anti-IgG	1. Label 2 test tubes for positive and negative controls. 2. Add 2 drops of anti-IgG to each tube. 3. Add 1 drop of check cells to the positive tube. 4. Add 1 drop of A_1 cells to the negative tube. 5. Serofuge for the immediate spin time listed on the serofuge. 6. Read and grade reaction using an agglutination viewer. 7. Immediately record results on the QC form. 8. Expected results: a. Positive = ≥2+ b. Negative = 0

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Reagent	Action
Anti-C3b, C3d	1. Label 2 test tubes for positive and negative controls. 2. Add 2 drops of anti-C3 to both tubes. 3. Add 1 drops of complement check cells to the positive tube. 4. Add 1 drop of B cells to the negative tube. 5. Mix gently. 6. Serofuge for the immediate spin time listed on the serofuge. 7. Read and grade reaction using an agglutination viewer. 8. Immediately record results on the QC form. 9. Incubate the negative tubes at room temperature for up to 5 minutes. 10. Serofuge for the immediate spin time listed on the serofuge. 11. Read and grade reaction using an agglutination viewer. 12. Immediately record results on the QC form. 13. Expected results: a. Positive = ≥2+ b. Negative = 0
Check Cells	1. Label 2 test tubes for positive and negative controls. 2. Add 2 drops of anti-IgG to the positive tube. 3. Add 2 drops of albumin negative tube. 4. Add 1 drop of check cell to both tubes. 5. Mix gently. 6. Serofuge for the immediate spin time listed on the serofuge. 7. Read and grade reaction using an agglutination viewer. 8. Immediately record results on the QC form. 9. Expected results: c. Positive (both IgG and C3) = ≥2+ d. Negative = 0
Complement Check Cells	1. Label 2 test tubes for positive and negative controls. 2. Add 2 drops of anti-C3 to the positive tube. 3. Add 2 drops of albumin to the negative tube. 4. Add 1 drop of complement check cells to each tube. 5. Mix gently. 6. Serofuge for the immediate spin time listed on the serofuge. 7. Read and grade reaction using an agglutination viewer. 8. Immediately record results on the QC form. 9. Incubate negative reactions for 5 minutes at room temperature. 10. Serofuge for the immediate spin time listed on the serofuge. 11. Read and grade reaction using an agglutination viewer. 12. Immediately record results on the QC form. 13. Expected results: a. Positive = ≥2+ b. Negative = 0

Reagent	Action
Bovine Albumin	1. Label a tube for a negative control. 2. Add 2 drops of albumin to the negative control. 3. Add 1 drop of check cells to the negative control. 4. Mix gently. 5. Serofuge for the immediate spin time listed on the serofuge. 6. Read and grade reaction using an agglutination viewer. 7. Immediately record results on the QC form. 8. Expected results Negative = 0
Panoscreen I, II, and III, ImmuAdd LISS	1. Label 2 sets of tubes as positive and negative for screen cells I, II, and III (6 tubes total). 2. Add 2 drops of confidence antibody to each of the positive tubes. 3. Add 2 drops of albumin to each of the negative tubes. 4. Add 1 drop of the appropriate screen cell (I, II, or III) to each of the tubes. 5. Add 2 drops of ImmuAdd LISS to each of the 6 tubes. 6. Incubate 15-30 minutes at 36-38°C. 7. Wash a minimum of 3 times with saline. 8. Add 2 drops of anti-IgG to each tube. 9. Mix gently. 10. Serofuge for the AHG time listed on the serofuge. 11. Read and grade reaction using an agglutination viewer. 12. Immediately record results on the QC form. 13. Add 1 drop of check cells to each negative tube. 14. Mix gently. 15. Serofuge for the AHG time listed on the serofuge. 16. Read and grade reaction using an agglutination viewer. 17. Immediately record results on the QC form. 18. Expected results: a. Positive for SC I, II, and III = 2-3+ b. Negative for SC I, II, and III = 0
Panocell-20, Panocell-16, Panocell-10	1. Label 2 tubes for positive and negative controls. 2. Add 1 drop of anti-Le^a to each tube. 3. Add 1 drop of one cell that is Le (a-b+) or Le (a-b-) to the negative tube. 4. Add 1 drop of one cell that is Le (a+b-) to the positive tube. 5. Mix gently. 6. Incubate the tubes at room temperature for 5-10 minutes. 7. Serofuge for the IS time listed on the serofuge. 8. Read and grade reaction using an agglutination viewer. 9. Immediately record results on the QC form. 10. Expected results: a. Positive for SC I, II, and III = $\geq$2+ b. Negative for SC I, II, and III = 0

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Reagent	Action
Confidence Kit	1. Label 2 tubes for controls. a. Label one tube A. b. Label one tube B. 2. Add 1 drop of Confidence Antibody to each of the tubes. 3. Add 1 drop of A_1 cell to the A tube. 4. Add 1 drop of B cell to the B tube. 5. Mix gently. 6. Serofuge for the AHG time listed on the serofuge. 7. Read and grade reaction using an agglutination viewer. 8. Immediately record results on the QC form. 9. Expected results: a. A_1 cell = $\geq$2+ b. B cell = $\geq$2+
Manual Capture Controls	1. Label the ends of a RS-3 strip for positive and negative controls. 2. Add 2 drops of Capture LISS to each well. 3. Add 1 drop of positive control sera to the 4 wells at the positive end of the strip. 4. Add 1 drop of negative control sera to the 4 wells at the negative end of the strip. 5. Incubate the strip at 36-38°C for 20 minutes. 6. Wash the strip with PBS. 7. Add 1 drop of indicator cells to each well. 8. Centrifuge for the screen indicator time/speed on the centrifuge. 9. Read and grade reactions. 10. Immediately record results on the QC form. 11. Expected results: a. Positive = $\geq$2+ b. Negative = 0
Antigen typing sera, Lectins, and	Refer to the antigen typing procedure for these reagents. Note: C, c, E, e, and K antisera may be quality controlled manually or on the Echo.

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Echo/Capture Reagents

Reagent	Perform the following QC test on the Echo
Echo WBCorQC, Anti-A, Anti B, Anti-D, Series 4 and Series 5, A_1 and B cells, CMT Plates, Monoclonal Control	ABO/Rh quality control Note: Anti-A, Anti-B, Anti-D Series 4, A_1 and B cells may be quality controlled manually or on the Echo
Capture LISS, Indicator Cells	Antibody screen quality control
Select Plates, DAT Positive Cells	Weak D quality control
Ready Screen 3 Plates, ReadyID Plates, Extend I plates, Extend II plates	These reagents contain built-in process controls; no reagent receipt QC is necessary

Kits

Reagent	Action
Sickle Screen Kit	Perform positive and negative controls per procedure.
Fetal Screen Kit	Perform positive and negative controls per procedure.
EluKit	Reagent receipt QC is not necessary. Eluates will never be used as the sole means for antibody identification.

Indicator Labels

Reagent	Action
HemoTemp II Temperature Indicators	1. Activate a HemoTemp II temperature indicator per procedure. 2. Apply the HemoTemp II temperature indicator to the saline thermometer bag. Ensure the bag has been stored in the blood bank refrigerator and is approximately 3-4°C in temperature. 3. Read and record the temperatures of both the HemoTemp II indicator and the calibrated thermometer in the refrigerator bag. 4. The temperatures must agree within ±1°C. Refer to the procedure to interpret the temperature of the HemoTemp II temperature indicator. 5. If results do not agree, return the temperature bag to the refrigerator until the temperature equilibrates and reread. If results are still out, the temperature indicators should not be used.
Rad-Sure Indicators	1. Apply two Rad-Sure labels to a red cell or platelet product. One Rad-Sure indicator should be from the current (in use) lot and the other from the new lot. The current lot indicator will document blood product irradiation while the new lot will be used for indicator QC. 2. Irradiate the blood product. 3. Verify that the "NOT" on both Rad-Sure indicators is obscured. QC fails and the labels should NOT be used if the NOT is not obscured. 4. Remove the new lot of Rad-Sure indicator from the blood product and allow the current lot indicator to remain.

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