TRAINING UPDATE

Lab Location:	SGMC, WOMC	**Date Implemented:**	1/27/2026
Department:	Blood Bank	**Due Date:**	2/13/2026

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Reagent Receipt and Acceptance
Description of change(s):
The following edits were made to the procedure: 1. When reagent receipt QC is done on the Vision, please print the reports that include the microtube results. Do not print the QC overview. 2. 0.8% resolve panel A and B will be QC'd with Le^a or Le^b like we QC the 3% panel. Simply run Le^a or Le^b QC using the new panel on the Vision. 3. 0.8% surgiscreen will require antibody screen QC. 4. Reagent receipt QC sheets get placed in the purple maintenance/QC binder. DO NOT PUT IN THE YELLOW BINDER.

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:	

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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 critical reagents and supplies into use.

4. DEFINITIONS

N/A

5. PROCEDURE

General Considerations

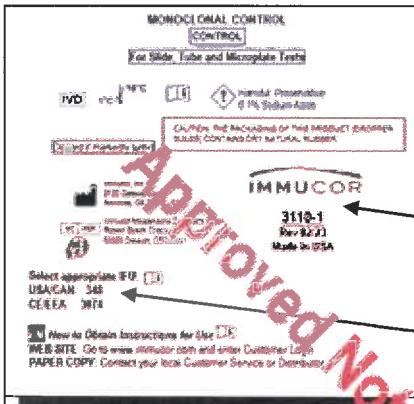
Step	Action
1	Only reagents and kits licensed by the Food and Drug Administration (FDA) will be used for patient and donor testing.
2	A manual of manufacturer's instructions will be maintained. These directions will be reviewed each time a new lot of reagent is received.
3	Reagents will be stored at the manufacturer's recommended temperature range when not in use. Opened reagents stored at room temperature will have their expiration dates shortened as required by the manufacturer's instructions.
4	All reagents poured or stored into a secondary container (such as saline) will be labeled with a laboratory reagent label. Prepared reagents may require assignment of an expiration date unless the manufacturer's expiration date is shorter. 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. F. Isopropyl alcohol will follow manufacturer expiration. Isopropyl alcohol will expire 1 year after opening if the manufacturer has not assigned an expiration date. G. Papain is good for 30 days after opening. H. Ortho QC is good for 14 days after opening. I. Reagent red blood cells that are stored on the Vision expire 5 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

Step	Action
	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 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.

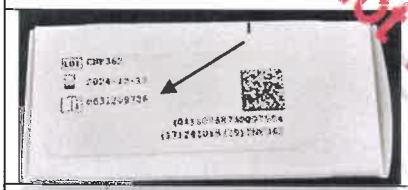
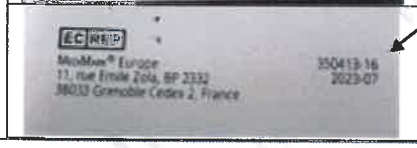
Supply Receipt

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.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4</td><td>Review the package insert version 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, log onto the manufacturer's website (listed on the supply) and download the new version of the insert. Compare the current and new inserts, document the changes made, and forward both to a supervisor for review.

<table>
<tr><td> 
</td><td>Werfen/Immucor does not put package inserts (IFU—instructions for use) in all products. They will add an information sheet that tells you which insert is in use.

This is NOT the insert number.

This is the insert number in use</td></tr>
<tr><td>  </td><td>Ortho insert and revision numbers are on the package next to the icon that looks like a book with an "i" on it.</td></tr>
<tr><td> 
</td><td>Streck insert and revision numbers are on the bottom corner of the insert.</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>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.</td></tr>
<tr><td>6</td><td>Place a red or yellow circle sticker with the received date on <u>each</u> package of reagent received and store the supplies/reagents in the designated location. Separate by product and lot number. Each new shipment of reagent must be quality controlled even when we have received the same lot of reagent in a previous shipment.
• Red stickers are placed on new lot numbers received.
• Yellow stickers are placed on new shipments of a lot number that has been received in a previous shipment.</td></tr>
<tr><td>7</td><td>Segregate each new shipment of reagents by placing a rubber band around like reagents from the same shipment. This allows other staff members to clearly locate all packages of a single product received in a particular shipment.</td></tr>
</table>

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 new **lot** and new **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	Reagent receipt quality control may be performed on the Vision, in Sunquest, or manually on paper depending upon the product being QC'd. Refer to appendix A for the specific QC requirements of each reagent.
3	If you are performing testing manually, on paper, complete a Reagent Receipt QC form. Fill 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. Lot number of kit (for Capture R controls, sickle controls, etc) *Note: All parts of a kit should be on the same QC sheet. F. Expiration date of kit (for Capture R controls, sickle controls, etc) G. Received date and tech initials H. Quantity received
3	Perform quality control per appendix A and document in one of the following ways: A. For QC performed on the Vision: a. Print the testing report using the order report which displays the column results. b. Highlight the reagent name, lot, and expiration and document the in-use date on the Vision report. c. Ensure that when reagent receipt QC is performed on a new lot of gel cards that the instrument used the new lot of gel cards. B. For QC performed in Sunquest, enter QC results and add a comment of reagent placed into use. C. Document manual QC on the Reagent Receipt QC form.
4	Document the date the new lot or shipment was placed into use and the method in which QC was performed on the Product Received Log.
5	Place the reagent receipt QC forms in the proper section of the purple QC/maintenance binder.

Step	Action
5	Place a green, circle sticker with the QC date on each box of reagent that will be placed into use following acceptable performance of quality control testing. Verify the quantity received using the Product Received Log and the dates written on the red/yellow circle stickers to ensure you have updated the entire shipment of that log of reagent. Place the green sticker directly on top of the red sticker that was placed upon receipt.
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.

6. RELATED DOCUMENTS

Form: Reagent Receipt QC (AG.F152)
Form: Product Received Log (AG.F149)
SOP: Supply Ordering, Receiving, and Restocking
SOP: Daily Reagent Quality Control
SOP: FWMC Daily Reagent Quality Control
SOP: Galileo Echo/Echo Lumena Daily Reagent Quality Control

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 zeros dropped due to new EDCS in use as of 10/7/13.	LBarrett	
1	2.12.14	Section 9: Added "Indicator Labels" section to appendix A.	SCodina	NCacciabeve

Version	Date	Reason for Revision	Revised By	Approved By
2	3.18.16	Section 5: Eliminated requirement to store outdated manufacturer's inserts; Added requirement to document kit lot and expiration for specific reagents.	SCodina	NCacciabeve
3	4.28.18	Header: Added WAH	LBarrett	NCacciabeve
4	7/10/20	Header: Changed WAH to WOMC Section 5: Updated ImmuAdd LISS to Gamma PeG. Added the requirement to QC both the current and previous lot of QC with the new fetal screen kit.	SCodina	NCacciabeve
5	8/11/21	Header: Added FWMC App A: Added anti-IgG gel cards and 0.8% Surgiscreen Footer: Changed prefix to AHC	SCodina	NCacciabeve
6	9.7.23	Updated instructions for reviewing insert version and date. Immucor will no longer provide inserts in product packaging.	SCodina	NCacciabeve
7	3.28.24	Added note that CM plates expire 9m after opening and 72h after removed from primary packaging per IFU.	SCodina	NCacciabeve
8	9.17.24	Added additional instructions for finding the IFU revision number on inserts. Updated some products to allow documentation on Echo report or in Sunquest. Updated instructions to reflect the new product received log.	SCodina	NCacciabeve
9	8.20.25	Removed references to Echo/Lumena and added Vision. Added expiration for isopropyl alcohol when the manufacturer does not assign. Removed Echo reagents and added Vision reagents to Appendix A.	SCodina	SBeltaifa
10	1.22.26	Added requirement to print reports with the microtube results from the Vision. Added instructions to place reagent receipt QC in the maintenance/QC binder. Added instructions to QC Resolve Panels A & B with Le^a. Updated QC for 0.8% Surgiscreen cells.	SCodina	SBeltaifa

9. ADDENDA AND APPENDICES

Appendix A: Quality Control Requirements by Reagent

Appendix A
Quality Control Requirements by Reagent

Testing Reagents

Reagent	Vision	Sunquest SGMC/WOMC	Sunquest FWMC	Manual QC
Anti-A	NA	Rack 1 tubes 1 & 5	Tubes 1 & 5	Same as Sunquest
Anti-B	NA	Rack 1 tubes 2 & 6	Tubes 2 & 6	Same as Sunquest
Anti-A,B	NA	Rack 1 tubes 3 & 7	Tubes 3 & 7	Same as Sunquest
Anti-D, Series 4	NA	Rack 1 tubes 4 & 8 (including weak D)	Tubes 4 & 8	Same as Sunquest
3% A1 Cells	NA	Rack 1 tubes 9 & 11	Tubes 9 & 11	Same as Sunquest
3% B Cells	NA	Rack 1 tubes 10 & 12	Tubes 10 & 12	Same as Sunquest
A2 Cells	NA	NA	NA	1. Label 2 test tubes for 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
AHG, polyspecific	NA	DAT QC tubes 2P and 2N	NA	Same as Sunquest
Anti-IgG	NA	DAT QC tubes 1P and 1N	NA	Same as Sunquest
Anti-C3b, C3d	NA	DAT QC tubes 3P and 3N	NA	Same as Sunquest

Reagent	Echo/Lumena	Sunquest SGMC/WOMC	Sunquest FWMC	Manual QC
Check Cells	NA	NA	NA	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: a. Positive (both IgG and C3) = ≥2+ b. Negative = 0
Complement Check Cells	NA	NA	NA	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. 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	Echo/Lumena	Sunquest SGMC/WOMC	Sunquest FWMC	Manual QC
Bovine Albumin or Monoclonal Control	NA	NA	NA	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, Gamma PeG	NA	Rack 2 P[illegible] QC Tubes 1P, [illegible], 1N, 2N, 3N	NA	Same as Sunquest
Anti-IgG gel cards	Diluent 2 QC	Gel Antibody Screen QC	Gel QC	Same as Sunquest
0.8% Surgiscreen I, II, III	AbScr QC	Gel Antibody Screen QC	Gel QC	Same as Sunquest
Buffered Gel Card	Buffered Card QC	NA	NA	NA
MTS Diluent 2	Diluent 2 QC	NA	NA	NA
MTS Diluent 2 Plus	ABO/Rh QC	NA	NA	NA
ABD and Reverse Gel Cards	ABO/Rh	NA	NA	NA
Panocell-20, Panocell-16, Panocell-10	NA	NA	NA	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 Le^a-positive cell **b.** Negative for Le^a-negative cell

Reagent	Echo/Lumena	Sunquest SGMC/WOMC	Sunquest FWMC	Manual QC
0.8% Resolve Panel A and Resolve Panel B	Antigen typing QC with Le[a]	NA	NA	NA
Confidence Kit	NA	NA	NA	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+
Antiserum and Lectins	Antigen typing QC per procedure	NA	NA	QC per antigen typing procedure and manufacturer's instructions
Sickle Dex and Sickle Chex	NA	NA	NA	Perform positive and negative controls per procedure.
Fetal Screen Kit	NA	NA	NA	Perform positive and negative controls from both the current and previous kit lot per procedure. Document this on the QC sheet using the lot number of the control and "pos" or "neg." All four controls must be within the acceptable range.
EluKit	Reagent receipt QC is not necessary. Eluates will never be used as the sole means for antibody identification.			
Rad-Sure Indicators	NA	NA	NA	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. Remove the new lot of Rad-Sure indicator from the blood product and allow the current lot indicator to remain.

Reagent	Echo/Lumena	Sunquest SGMC/WOMC	Sunquest FWMC	Manual QC
HemoTemp II Temperature Indicators	NA	NA	NA	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.
Blood product bags, tubing, syringes, etc.	NA	NA	NA	Visual inspection only; this does not need to be documented on the reagent receipt QC log