TRAINING UPDATE

Lab Location:	FWMC	**Date Implemented:**	3/25/25
Department:	Blood Bank	**Due Date:**	4/8/25

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
FWMC Daily Reagent Quality Control
Description of change(s):
Recently, we have had issues at all sites where staff members have failed to perform QC during their shift. Each shift is supposed to verify that QC was performed during the previous shift. In every case where QC was missed, the following shift also failed to identify the omission and complete QC. The procedure was updated to require each shift to look at the daily QC results using SmarTerm function QCR. The requirement was added to the daily duties checklist to remind staff to perform this function. If you note any errors in QC for a previous shift or if QC was not performed, you are required to complete QC and fill out an IQE event.

Adventist HealthCare

Month/Year:

Daily Reports and Tasks Form

Location:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Day Shift																															
Blood Bank Backup (BEX,BBR6,BBR15)																															
Product File List (BBR2, allocated)																															
Rack 1 QC																															
Verify Night Shift QC Reaction Results and Maintenance Tasks																															
Arrange Blood Inventory by Expiration Date																															
Daily Temperatures and Change Charts on Mon																															
Microscope QC																															
Detailed Inventory (BBR2, INV, PLAS/CRYG) First w/e of Mo																															
Transferred unit report to Inova--BBR9 (1st of month)																															
Evening Shift																															
Rack 2 QC																															
Verify Dayshift QC Reaction Results and Maintenance Tasks																															
Verify Day																															
Centrifuge Maintenance																															
Cell Washer Maintenance																															
Plasma Thawer Maintenance																															
Surgery Schedule																															
Adjust Standing Orders As Needed (BBR13)																															
Cell Washer Weekly Maintenance (Date and Tech Code)																															
Plasma Thawer Weekly Maintenance (Date and Tech Code)																															
Monthly Centrifuge QC																															
Discard Reagent Cells >3 Months Old																															
Night Shift																															
Expired Allocation List																															
Blood Bank Expired Crossmatches (BEC)																															
Expired Blood Product List (BBR4)																															
BSU Units on BBR4 to Appropriate Status																															
Issued, Unreported Units List (BBR5)																															
Blood Issue Finalization (BIF)																															
Short Outdate Summary (BBR12)																															
DAT Rack QC																															
Echo Maintenance and QC																															
Verify Evening Shift QC Reaction Results and Maint Tasks																															
Eyewash Check (Date and Tech Code)																															
Discard Old Unit Segments (First Day of Month)																															
Group Lead																															
Review of AbID and Antigen Typing																															
Daily Rh negative Results Report																															
Patient AD Data Update (BBR8)																															
Quality Assurance Report (BBR7)																															
Incomplete Reaction Result Log (BBR18)																															
Merge Log (LO11)																															
Overdue Test Log (LO2) (Weekly)																															
Review of QC Results (QCR)																															
Reagent Receipt QC Weekly (Date and Tech Code)																															
Verification of Backup Monthly (Date and Tech Code)																															

Note: Reports are routinely run on a daily basis. However, some reports may not be generated on weekends, holidays, or days in which workload is unusually high. If the report is not generated for a given day, place a hashmark (/) in the box that corresponds to the day on which the report was not performed.

Supervisor Review: _____ **Date:** _____

Non-Technical SOP

Title	**FWMC Daily Reagent Quality Control**	
Prepared by	Stephanie Codina	Date: 7.30.2021
Owner	Stephanie Codina	Date: 7.30.2021

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

Commercial antisera and reagent red blood cells are tested daily and prior to being placed into use for patient testing to confirm that they react as expected. Reagents in use are tested with known samples and the results are documented.

2. SCOPE

This procedure applies to commercial antisera and reagent red cells. Each reagent is tested daily and prior to being placed into use for patient testing.

3. RESPONSIBILITY

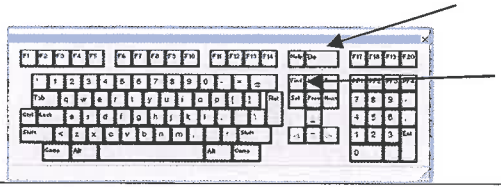
All blood bank staff members must understand and adhere to this procedure for performing reagent quality control.

4. DEFINITIONS

N/A

5. PROCEDURE

General Notes

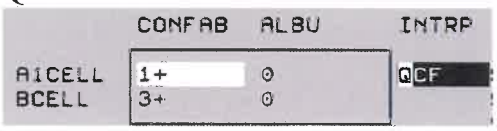
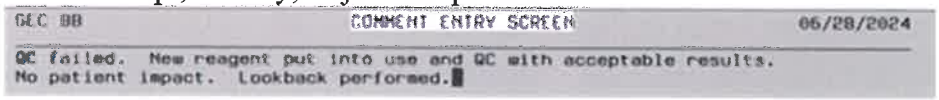
Step	Action
1	Quick Notes: LAB ID = FWBB RACK ID = FW1 BATTERY = DRQC AMR = Accept, Reject, Modify
2	Click the picture of the keyboard at the top of the screen to utilize the function keys. 
3	Once the keyboard is open, use your mouse to click the keys needed. The "Find" and "Do" keys are located here. 

Daily Quality Control

Step	Action
1	Remove reagent and quality control racks from the refrigerator to allow reagents to come to room temperature.
2	Perform an inspection of reagents. A. Verify that the expiration date of each reagent has not been exceeded. B. Discard expired reagents and any reagents that will expire within 24 hours of quality control procedure. C. Discard reagents that will be depleted during the day. D. Replace discarded reagents with new reagents.
3	Set up gel QC per instructions below and allow to incubate and centrifuge will the remainer of QC is performed.
4	Access Sunquest SmarTerm function **QCE** for Quality Control Entry. A. At the "Tech Code" prompt, type your tech code and press "tab." B. At the "Shift" prompt, press "tab." C. At the "Lab ID" prompt, type **FWBB** and press tab. D. At the "Bench/Rack" prompt, type **FW1** and press tab.

Step	Action
	If you are entering a new log or new shipment of reagent, follow the instruction in the section labeled "Reagent Receipt Process." Before continuing to the next step.
5	At the "Main Menu" screen, highlight, **5. Grid Result Entry** and press enter. A. At the "Date" prompt, press enter to default the current date. B. At the "Battery" prompt, type **DRQC** for daily reagent quality control. C. At the "Retest" prompt, a. Type **N** and press enter if this is the first time QC has been run for the day. b. Type **Y** and enter if QC has already been performed for the current day and is being repeated. Reasons for repeat include: i. New lot or shipment of reagent is being placed into use after QC was performed for the current day. ii. QC failed and is being repeated after corrective actions have been taken. Repeat QC only requires QC of the applicable reagents. You do not have to repeat QC of all reagents.
6	A "Rack Lot Association" screen will appear. Note: the reagents display in alphabetical order. A. Click on the keyboard icon to display the keyboard. B. Click the **Find** key (located on the electronic keyboard) to display the lots of a particular reagent in use. C. Highlight the lot that corresponds to the lot printed on the reagent. Verify the correct expiration date is listed and click enter. D. Repeat these steps until all reagent lots and expiration dates have been entered. E. For "ROK" always enter a lot of "OK" with no expiration date. This is a computer placeholder for the visual inspection. F. Click on the **Do** key to move to the next screen.
7	The "Grid Result Entry" screen will appear. A. Visually inspect all reagents for evidence of contamination or deterioration (marked turbidity or precipitation of antisera, hemolysis of red cells). B. Enter the visual inspection for each reagent. a. Enter **Y** if the visual inspection passed. b. Enter **N** if the visual inspection failed. Do not use any reagents that did not pass visual inspection. Discard and place a new reagent into use. Write a PI/variance. C. Press the "Enter" key to move to the next grid.
8	Perform the Immediate Spin portion of QC. A. Label 12 test tubes 1-12. B. Add antisera to the tubes. a. Add 1 drop of anti-A to tubes 1 and 5.

Step	Action
	b. Add 1 drop of anti-B to tubes 2 and 6. c. Add 1 drop of anti-A,B to tubes 3 and 7. d. Add 1 drop of anti-D to tubes 4 and 8. e. Add 1 drop of confidence antibody to tubes 9 and 10. f. Add 1 drop of albumin to tubes 11 and 12. C. Visually inspect each tube to ensure the reagent is present. D. Add cells to the tubes. a. Add 1 drop of confidence 1 to tubes 1, 2, 3, and 4. b. Add 1 drop of confidence 2 to tubes 5, 6, 7, and 8. c. Add 1 drop of A1 cell to tubes 9 and 11. d. Add 1 drop of B cell to tubes 10 and 12. E. Gently mix each tube and serofuge for the immediate spin phase time listed on the serofuge (generally 15 seconds). F. Read one tube at a time macroscopically for agglutination using an agglutination viewer and immediately record results in the computer. G. QC1 Grid a. Tube 1 (from left) = Anti-A + Confidence 1 b. Tube 2 = Anti-B + Confidence 1 c. Tube 3 = Anti-A,B + Confidence 1 d. Tube 4 = Anti-D + Confidence 1 H. QC 2 Grid a. Tube 5 (from left) = Anti-A + Confidence 2 b. Tube 6 = Anti-B + Confidence 2 c. Tube 7 = Anti-A,B + Confidence 2 d. Tube 8 = Anti-D + Confidence 2 I. QC 3 Grid a. Tube 9 (left, top) = Confidence Antibody + A1 Cell b. Tube 10 (left, bottom) = Confidence Antibody + B Cell c. Tube 11 (right, top) = Albumin + A1 Cell d. Tube 12 (right, bottom) = Albumin + B Cell
9	Perform the Gel portion of QC. Note: It is acceptable to set up, incubate, and centrifuge gel QC while performing the other parts as long as results are entered at the time they are read. A. Obtain an Anti-IgG gel card. Visually inspect the gel card before use. Each microtube should have a clear liquid layer on top of opaque gel. Do not use gel cards if the gel matrix is absent or the liquid level in the microtube is at or below the top of the gel matrix. Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts. Do not use cards if foil seals appear damaged or opened. B. Label the 3 microtubes with "Confidence Antibody" and the other 3 with "Albumin" label the individual microtubes as 1, 2, and 3. C. Remove the foil seal from the gel card. Inspect the gel card to ensure that residual film does not block the opening of any microtube. D. Add 50 uL of red blood cells to each microtube. Do not allow the pipette tip to touch the microtube. Erroneous results due to carryover may occur.

Step	Action
	a. Add 50 µL of screen cell I to both microtubes labeled "1." b. Add 50 µL of screen cell II to both microtubes labeled "2." c. Add 50 µL of screen cell III to both microtubes labeled "3." E. Add 25 µL Confidence Antibody to the three tubes labeled as such. F. Add 25 µL of albumin to the three tubes labeled as such. G. Incubate the gel card for 15 minutes at 35-39°C. Do not allow incubation to exceed 40 minutes. H. After incubation, centrifuge the gel card at the preset conditions. I. After centrifugation, remove the gel card from the centrifuge. J. Observe and read macroscopically the front and back of each microtube for agglutination and/or hemolysis and record reactions. If either side of the microtube is positive, the reaction is considered to be positive. K. Record results immediately in the Gel QC grid.
10	As you enter results, Sunquest will interpret whether QC is acceptable. A. If acceptable, the interpretation will update to "QCP." B. If unacceptable, the interpretation will update to "QCF" and the failed QC result will be backlit.  C. Type the * asterisk key to open the "Modify, Accept, Reject, or Comment" fields. D. Enter a comment if a new lot or shipment of reagent was placed into use (Ex: New shipment of albumin lot 123456 placed into use). E. Accept the result to save.
11	If any of the QC results failed, utilize the "Out of Range Quality Control" section of this procedure to troubleshoot. Sunquest will require a failure code and comment. A. Enter the appropriate Quality Control modifier code from Appendix A. B. At the "Edit Comment" prompt, type "Y." C. Type a comment that outlines the problem, corrective actions, and patient impact. D. Press the **F1** key to save. E. Type the **E** key and enter to exit. F. Select Accept, Modify, Reject and press enter. 

Reagent Receipt Process

Step	Action
1	This process is followed when placing a new bottle or new shipment of reagent into use.
2	Access SmarTerm function **QCE** (QC Entry).
3	Select **1. Lot Entry.**
4	At the "MFG Code" prompt, type one of the following and press the **tab** key. A. **WER** for Werfen/Immucor. B. **ORT** for Ortho.
5	At the "Lot Number" prompt, type the lot number from the reagent and press the **tab** key.
6	At the "Item(s)" prompt, type the mnemonic that corresponds to the reagent being entered. If more than one reagent has the same lot number (such as with Surgiscreen or Confidence), type each of the mnemonics separated by a comma. A. A1 Cell = A1CELL B. Albumin = ALBU C. Anti-A = ANTIA D. Anti-A,B = ANTIAB E. Anti-B = ANTIB F. Anti-D = ANTID G. B Cell = BCELL H. Confidence Kit = CONF1,CONF2,CONFAB,CNF I. Diluent 2 = DIL2 J. Anti-IgG Gel Card = IGGGEL K. Surgiscreen = SURSC1,SURSC2,SURSC3,SURSCN
7	Select the lot number to inactivate (the one being taken out of use) or select "New Shipment" from the pop-up menu.
8	Press **tab** to bypass the procedure(s) prompt.
9	At the "Received Date" prompt, type the date on which the reagent/shipment was received in the lab from the Product Received Log and press **tab**.
10	At the "Active Date" prompt, type **T** for today and press the **tab** key.
11	Press **tab** to bypass the "Inactive Date" prompt.
12	At the "Expiration Date" prompt, type the expiration date of the reagent.

Step	Action
13	At the "Quantity" prompt, type the quantity of reagent received from the Product Received Log.
14	Press **tab** to bypass the notes section.
15	Highlight **Accept** and press **enter** to save the lot.
16	When performing QC, you must enter the new lot next to the reagent name on the "Rack Lot Association" screen to officially put the reagent into use.
17	Document the date on which the new lot/shipment of reagent was placed into use on the Product Received Log.

Out of Range Quality Control

Step	Action
1	**DO NOT** report patient results if the quality control result is out of acceptable range.
2	Use problem solving techniques to determine the cause of unacceptable quality control. Correct problems as noted. Techniques include, but are not limited to, the following: A. Verify that the procedure was followed as written. B. Check reagents or control materials for deterioration. C. Verify the proper amount of reagent/control was used for testing. D. Verify instrument function, if applicable. E. Verify that reagents were at room temperature (18-30°C or other temperature defined by the manufacturer) when quality control was performed.
3	Repeat quality control once corrective action has been performed or potential issues have been ruled out. You only need to repeat QC on the reagents that failed. It may be necessary to reanalyze the failed run or other specimens run since the last acceptable QC results were obtained to ensure results area accurate and reliable.
4	Add a comment that documents the following: A. Evaluation of problem B. Corrective action taken to resolve the situation C. Impact on patient results

Downtime Process

Step	Action
1	Obtain a copy of the "FWMC Downtime Blood Bank Quality Control" form.
2	Record the date on which QC was performed and the tech completing QC in the designated spots.
3	Record the lot number and expiration date of each reagent that will be quality controlled on the form. A. Verify the expiration date of reach reagent has not been exceeded. B. Discard expired reagents and any reagents that will expire within 24 hours of quality control procedure. C. Discard reagents that will run out during the day. D. Replace discarded reagents with new bottles.
4	Visually inspect all reagents for evidence of contamination or deterioration (marked turbidity or precipitation of antisera, hemolysis of red cells). A. Document the appearance of each reagent on the downtime form. a. Document **S** if the reagent has a satisfactory appearance. b. Document **U** if the reagent has an unsatisfactory appearance. B. Replace reagents with an unsatisfactory appearance. a. Do not use reagents with an unsatisfactory appearance for patient testing. b. Write a PI/Variance to document the reagent problem.
5	Follow the instructions above to set up QC. Document results on the downtime form.
6	Determine whether quality control results are acceptable by comparing the results obtained to the expected values for each tube. Document the QC interpretation by circling Pass or Fail on the downtime form.
7	Enter QC in Sunquest when the computer system is operational. Sunquest will not allow staff to backdate QC. If QC was performed on downtime and it was not entered on the same calendar day it was performed, add a comment indicating QC was performed on downtime and retroactively entered into Sunquest. A. Enter QC per procedure above. B. At the "Accept, Modify, Reject, Comment" prompt, select **Comment.** C. Enter the comment and press the **F1** key to save. D. At the "Command" prompt, type **E** to enter and save. E. At the "Save and Exit: Are you sure?" prompt, type **Y** and enter to save. F. The screen will return to the Accept, Modify, Reject prompt. Accept the results to save.
8	Document the tech code of the person that entered the results and the date of entry on the downtime form.

Step	Action
9	File the completed form in the Blood Bank QC Manual.

QC Verification

Step	Action
1	Dayshift is responsible for verifying the QC results. This must be done at the beginning of the shift.
2	Access the QC results in Sunquest. A. Access Sunquest SmarTerm function **QCR**. B. Select printer **0** to print on screen. C. Select option 7, **Rack Result Report**. D. At the "Lab ID" prompt, type **FWBB**. E. At the "Modify, Accept, Reject" prompt, select **M** to modify the date. F. Enter the desired **Start Date** and **End Date** and press enter until you get to the "Modify, Accept, Reject" prompt. G. Select **A** to accept.
3	The report will print on the screen. A. Verify that QC has been performed. B. Verify that results are acceptable. C. Verify none of the expiration dates have been exceeded or will be exceeded before QC is run again.
4	QC must be performed/repeated if any discrepancies are noted. Patient impact must be assessed. Notify the supervisor immediately if patient impact was identified.

Weekly QC Review

Step	Action
1	The group lead or designee is responsible for reviewing QC results weekly.
2	Access the QC results in Sunquest. A. Access Sunquest SmarTerm function **QCR** for QC reports. B. Select option **7. Rack Result Report**. C. At the "Lab ID" prompt, type **FWBB**. D. At the "Modify, Accept, Reject" prompt, you can accept the default or modify to change the date range.

Step	Action
3	The QC results that were performed and documented during the timeframe selected will appear on the screen. Review the results to ensure the following: A. QC was performed each day on which patients were tested. B. QC results were within acceptable limits. C. If outliers are noted, a. Verify the appropriate corrective actions and patient impact are documented. b. Verify that QC was repeated and found acceptable before patient testing was performed. D. If a new lot or shipment of reagent was placed into use, ensure it was properly quality controlled prior to patient testing and documented on the product received log.
4	Document weekly QC review on the Daily Reports and Tasks Form.

Expected Results

Step	Action
1	**Daily Quality Control**

Tube	Expected Result
1	2+, 3+, 4+
2	2+, 3+, 4+
3	2+, 3+, 4+
4	0
5	0
6	0
7	0
8	2+, 3+, 4+
9	2+, 3+, 4+
10	2+, 3+, 4+
11	0
12	0
Confidence Ab Gel (microtubes 1, 2, & 3)	1+, 2+, 3+, 4+
Albumin Gel (microtubes 1, 2, & 3)	0

6. RELATED DOCUMENTS

SOP: Blood Bank Reaction Grading
SOP: Blood Bank Reagents and Controls Policy
Form: FWMC Downtime Blood Bank Quality Control Form (AG.F48)
Form: Daily Reports and Tasks Form (AG.F129)

7. REFERENCES

Ortho Confidence System Manufacturer's Instructions, Pub No J65523_EN, version e631209724. Ortho Clinical Diagnostics. Raritan, New Jersey.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
1	7/18/24	Section 5: Added "General Notes"; Revised QC process; added "Downtime Process"; added "Weekly QC review"; Revised "Expected results". Section 9: Added Appendix A	S Codina	S Beltaifa
2	8/2/24	Added the "Reagent Receipt Process."	SCodina	SBeltaifa
3	3/21/25	Added QC Verification section.	SCodina	SBeltaifa

9. ADDENDA AND APPENDICES

Appendix A—Quality Control Modifier Codes

Appendix A
Quality Control Modifier Codes

Code	Translation
AC10	Patient testing suspended
AC28	Reagent change lookback not indicated (No patients tested since last acceptable QC)
AC29	Reagent change lookback performed and acceptable
AC34	Test/assay repeated QC in range
AC39	Reagent repeat with fresh reagent failed, patient testing suspended
NPTR	No patient run between last successful and failed QC run, lookback not indicated
R21	Notified supervisor