TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	2.5.2014
Department:	Blood Bank	**Due Date:**	2.28.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Galileo Echo Daily Reagent Quality Control

Description of change(s):

- We recently received a Technical Communication from Immucor offering additional guidance for troubleshooting QC failures. The Technical Communication was signed off by BB staff members in MTS.

- I added the information in that Technical Communication to the "Out of Range Quality Control" section of this procedure.

- I added the expected reaction charts in appendix C. Please note, the Echo grades reactions as a percent from 1-100. The numbers represent the acceptable range.

Non-Technical SOP

Title	**Galileo Echo Daily Reagent Quality Control**	
Prepared by	Stephanie Codina	Date: 6/23/2011
Owner	Stephanie Codina	Date: 6/23/2011

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:	

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

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1. PURPOSE

Operators run quality control (QC) assays each day the instrument operates and when a new lot of reagent is placed on the instrument. Galileo Echo quality control must run successfully before sample processing can be completed and before results will be released. QC verifies reagents react appropriately, verifies the instrument operates correctly, and checks for deteriorating reagent sensitivity and specificity. QC results are valid up to a maximum of 24 hours. This procedure describes the steps that will be followed to perform QC on the Galileo Echo.

2. SCOPE

This procedure applies to the Galileo Echo analyzer.

3. RESPONSIBILITY

All blood bank staff members must understand how to perform QC on the Galileo Echo and must perform QC as outlined by this procedure.

4. DEFINITIONS

N/A

5. PROCEDURE

Step	Action
1	Whole Blood corQC (WB corQC; Immucor Cat. # 66090, or equivalent) is a set of four manufactured controls used for quality control of the Galileo Echo. A. Tube 1 a. A-positive, C+, c-, E-, e+, K+ red blood cells b. Anti-B and anti-c in diluent B. Tube 2 a. B-negative, C-, c+, E-, e+, K- red blood cells b. Anti-A and anti-D in diluent C. Tube 3 a. O-positive, C-, c+, E+, e-, K- red blood cells b. Anti-A and anti-B in diluent D. Tube 4 a. O-positive, C+, c+, E+, e+, K- red blood cells b. Anti-A and anti B in diluent c. Note: Tube 4 only needs to be run for QC of antisera
2	Ensure the WB corQC tubes and all reagents are at room temperature before placing them on the instrument. Cold specimens and/or reagents will yield false positive and unreadable results.
3	Centrifuge the WB corQC tubes for 5-10 minutes at 3000-3600 rpm before use.
4	Load reagents onto the instrument. See appendix A for a list of reagents used for each assay. o Ensure there are no bubbles in the reagents. o Remove the tops to the reagent bottles. o Gently mix red cell reagents to resuspend contents. o Ensure there is one stirball in each red cell reagent. o Indicator cells expire 24 hours after the stirball is added. o DAT cells expire 7 days after the stirball is added or after 72 hours if left at room temperature, on the instrument o Ensure the barcode of each reagent can be seen through the gap on the right side of the reagent rack. If more than one barcode is on a reagent, use the barcode that does not have an "ABS" in it. o Quality control will not run if more than one bottle of a reagent is loaded on the instrument.
5	Remove the lids from the WB corQC tubes and position the tubes in the appropriate specimen rack. Ensure the barcode labels can be seen through the gap on the left side of the sample rack. Note: Tube 4 only needs to be run when antigen typing is being QC'd.
6	Slide the sample rack into the sample loading bay.

Step	Action
7	Verify all barcodes have been scanned successfully.
8	Click the "Run Test Wizard" icon on the Tool Bar to display the "Select Tests" window.
9	Select the following assays from the list of selected tests then click on the "Next" button. **These assays will QC all reagents.** A. Group Screen (Type & Screen) B. Antigen typing, only on each day of use for each antigen that will be performed. The following WB corQC tubes will be required to QC antigen typing. a. C requires tubes 2 and 4. b. c requires tubes 1 and 4. c. E requires tubes 2 and 4. d. e requires tubes 3 and 4. e. Kell requires tubes 1 and 4. f. CcEe battery requires tubes 1, 2, 3, & 4.
10	The "Select Samples" window will be displayed.
11	Select the WB corQC samples and click on the "Next" button.
12	The "STAT Tests and Priorities" window will display. Click on the "Next" button.
13	The "Supplies" window will display a list of reagents and micro-well strips that will need to be added to the instrument. Add the appropriate reagents. A. Ensure all reagents are at room temperature before running. B. Remove caps from all reagents before placing them on the instrument. C. Ensure each cellular reagent contains a single stir ball. D. Do not place more than one bottle of a reagent or one lot of a particular strip on the instrument. The instrument will not run QC with more than one bottle of reagent or lot of strip in place.
14	Review the information in the "Confirm Test" window and click on the "Begin Tests" button to begin the assays.

Step	Action
15	The instrument will run the quality control specimens and determine if the QC was run "successfully." Refer to appendix B for a list of expected results. A. If the QC test results are accepted, the next required QC time for the reagents used is moved forward 24 hours. QC does not need to be repeated unless a new lot number of reagent is placed on the instrument. B. If the QC test results are unacceptable (QC Failure), results of all other tests included in the QC run are invalidated. If QC fails, the cause of the failure should be identified and QC repeated. After a QC failure, no more tests using the affected reagents may be started unless the required WB corQC tubes are included in the run.
16	Print and review the quality control results. A. Sign the quality control document indicating your review. B. File the quality control document in the Galileo Echo Quality Control book by day of month. a. The group lead will review quality control results weekly. b. The manager or supervisor will review quality control results monthly.

Out of Range Quality Control

Step	Action
1	**DO NOT** report patient results if the quality control result is out of acceptable range.

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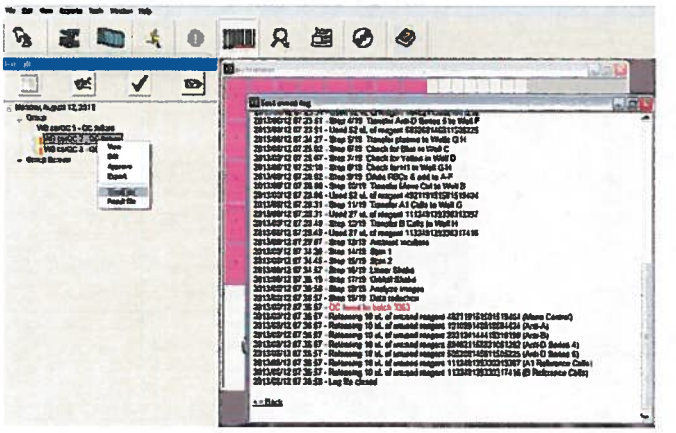
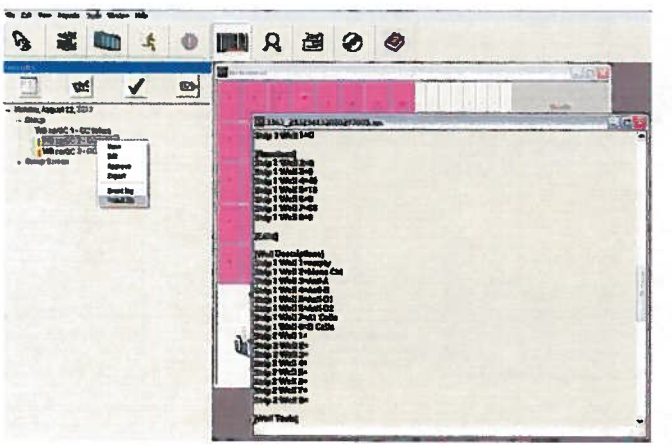
Step	Action
2	Determine the cause of the QC failure. A. Locate the batch number of the failed QC run at the top of the test results page. B. From the results window on the main instrument page, right click on any one of the failed WBCor QC samples. C. Select "event log." D. All failed QC batches will be printed in red color. Look for the red event with the batch number identified in step a.  Note: If multiple QC batches are running at one time and QC fails for a single batch, the instrument will automatically fail all other batches running that have reagents in common with the failed QC. E. Right click on the batch number. F. Scroll down until you see the reactions.  G. Match the reaction numbers with the expected reaction numbers listed in Appendix C for the corresponding assays to determine which well(s) are responsible for the QC failure. Well scores must fall into the range listed in appendix C for a given control/well. H. Review the well image to help determine why QC may have failed.

Step	Action
3	Use problem solving techniques to determine the cause 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. Ensure stirballs have been added to all red cell reagents. D. Verify the proper amount of reagent/control was used for testing. E. Verify instrument function, if applicable. F. Verify that reagents were at room temperature (18-30°C or other temperature defined by the manufacturer) when quality control was performed.
4	Repeat quality control once corrective action has been performed or potential issues have been ruled out. It may be necessary to reanalyze the failed run or other specimens run since the last acceptable QC results were obtained to ensure results are accurate and reliable.
5	Document the following on the quality control form: A. Evaluation of problem B. Corrective action taken to resolve the situation C. Impact on patient results
6	If the Echo is out of service for any reason: A. Manual Capture will be used for antibody screen and antibody identification procedures. B. Manual tube testing will be used for ABO, Rh, and antigen typing. C. LISS tube methodology will be used for crossmatching and as a backup if both the Galileo Echo and Manual Capture procedures are unavailable.

6. RELATED DOCUMENTS

SOP: Blood Bank Reaction Grading
SOP: Reagents and Controls Policy for Transfusion Services
SOP: Quality Control Program, Transfusion Services

7. REFERENCES

1. Galileo Echo Operator Manual, version ECO-001-100, ImmucorGamma, Norcross, GA.
2. Galileo Echo Training Guide, version ECO-003-200, ImmucorGamma, Norcross, GA.
3. Technical Communication CC-13-023-01 issued 10.9.2013. ImmucorGamma, Norcross, GA.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
000	1.17.2012	Section 5: Added "Out of Range Quality Control"	SCodina	NCacciabeve
001	9.25.2012	Section 5: Removed requirement to QC weak D daily; Immucor does not require this for our test menu. Changed backup method for crossmatching from manual capture to LISS tube.	SCodina	NCacciabeve
002	1.29.14	Section 5: Added step 2 in "Out of Range QC" Section 9: Added appendix C following manufacturer notification.	SCodina	NCacciabeve
		Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	LBarrett	

9. ADDENDA AND APPENDICES

Appendix A: Reagents Used by Assay
Appendix B: Expected Results for WBcorQC Reagent Quality Control
Appendix C: WBcorQC Reaction Charts

Appendix A

Reagents Used by Assay

ABO/Rh Testing	
Reagent	Supplier and Catalog Number
Anti-A, Series 1	Immucor Cat. #6400, or equivalent
Anti-B, Series 3	Immucor Cat. #6406, or equivalent
Anti-D, Series 4	Immucor Cat. #6412, or equivalent
Anti-D, Series 5	Immucor Cat. #6414, or equivalent
A_1 and B Reference Cells	Immucor Cat. #2345, or equivalent
Monoclonal control	Immucor Cat. #66089, or equivalent
CMT Plates	Immucor Cat. #89000, or equivalent
Isotonic Saline, Certified Blood Bank Saline	Fisher, Cat. #23535435 or equivalent
pHix Phosphate Buffer Concentrate	Immucor, Cat. #5070 or equivalent

Antibody Screen Testing	
Reagent	Supplier and Catalog Number
Capture-R, Ready Screen (3) Plates	Immucor Cat. #6440, or equivalent
Capture LISS	Immucor Cat. #6420, or equivalent
Capture-R Indicator Red Cells	Immucor Cat. #6428, or equivalent
Isotonic Saline, Certified Blood Bank Saline	Fisher, Cat. #23535435 or equivalent
pHix Phosphate Buffer Concentrate	Immucor, Cat. #5070 or equivalent

Antigen Typing	
Reagent	Supplier and Catalog Number
One or more of the following: o Anti-Kell GammaClone o Anti-C GammaClone o Anti-c Series 1 o Anti-E GammaClone o Anti-e GammaClone	Immucor Cat. # or equivalent o 66451 o 66421 o 66425 o 66422 o 66424
CMT Plates	Immucor Cat. #89000, or equivalent
Monoclonal Control	Immucor Cat. #66089, or equivalent
Specimen Diluent	Immucor Cat #66052, or equivalent
Isotonic Saline, Certified Blood Bank Saline	Fisher, Cat. #23535435 or equivalent
pHix Phosphate Buffer Concentrate	Immucor, Cat. #5070 or equivalent

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Appendix B

Expected Results for WBcorQC Reagent Quality Control

	Tube 1	Tube 2	Tube 3	Tube 4
ABO/Rh	A-Positive	B-Negative	O-Positive	O-Positive
Antibody Screen	Positive	Positive	Negative	Negative
C (big C) antigen typing	Positive	Negative	Negative	Positive
c (little c) antigen typing	Negative	Positive	Positive	Positive
E (big E) antigen typing	Negative	Negative	Positive	Positive
e (little e) antigen typing	Positive	Positive	Negative	Positive
Kell antigen typing	Positive	Negative	Negative	Negative

Appendix C

WBcorQC Reaction Charts

Group Screen							
Strip 1 Reactions	**Control** Well 2	**Anti-A** Well 3	**Anti-B** Well 4	**Anti-D1** Well 5	**Anti-D2** Well 6	**A1 Cells** Well 7	**B Cells** Well 8
WBcorQC 1	0-2	29-100	0-2	10-100	10-100	0-2	10-100
WBcorQC 2	0-2	0-2	29-100	0-2	0-2	10-100	0-2
WBcorQC 3	0-2	0-2	0-2	10-100	10-100	10-100	10-100
Strip 2 Reactions	**Cell 1** Well 1	**Cell 2** Well 2	**Cell 3** Well 3	**Control** Well 4			
WBcorQC 1	0-4	10-100	10-100	10-100			
WBcorQC 2	10-100	10-100	0-4	10-100			
WBcorQC 3	0-4	0-4	0-4	10-100			

Group							
Strip 1 Reactions	**Control** Well 2	**Anti-A** Well 3	**Anti-B** Well 4	**Anti-D1** Well 5	**Anti-D2** Well 6	**A1 Cells** Well 7	**B Cells** Well 8
WBcorQC 1	0-2	29-100	0-2	10-100	10-100	0-2	10-100
WBcorQC 2	0-2	0-2	29-100	0-2	0-2	10-100	0-2
WBcorQC 3	0-2	0-2	0-2	10-100	10-100	10-100	10-100

Screen				
Strip 1 Reactions	**Cell 1** Well 1	**Cell 2** Well 2	**Cell 3** Well 3	**Control** Well 4
WBcorQC 1	0-4	10-100	10-100	10-100
WBcorQC 2	10-100	10-100	0-4	10-100
WBcorQC 3	0-4	0-4	0-4	10-100

Weak D		
Strip 1 Reactions	**Anit-D1** Well 1	**Control** Well 2
WBcorQC 1	10-100	10-100
WBcorQC 2	0-4	10-100
WBcorQC 3	10-100	10-100

Phenotype					
CcEe					
Strip 1 Reactions	**Control** Well 1	**C** Well 2	**c** Well 3	**E** Well 6	**e** Well 7
WBcorQC 1	0-5	10-100	0-5	0-5	10-100
WBcorQC 2	0-5	0-5	10-100	0-5	10-100
WBcorQC 3	0-5	0-5	10-100	10-100	0-5
WBcorQC 4	0-5	10-100	10-100	10-100	10-100
Kell					
Strip 1 Reactions	**Control** Well 1	**K** Well 2			
WBcorQC 1	0-5	10-100			
WBcorQC 4	0-5	0-5			

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