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|  | **LABORATORY DEPARTMENT****POLICIES AND PROCEDURES** | **Department:****BLOOD BANK** |
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| **Galileo ECHO Operating Procedure** |

## Policy

1. The Galileo Echo Instrument is an automated Blood Bank analyzer which performs testing on donor and patient samples.
2. Two test methodologies are utilized in the ECHO system:
3. Hemagglutination is used for "Group" assays (Blood Types) using Coated Micro Typing (CMT) strips and liquid reagents for the detection and identification of ABO/Rh antigens and IgM antibodies.
4. Solid Phase Red Cell Adherence (SPRCA) is used for "Screen" assays using Capture-R strips and sensitized Indicator Cells for the detection of IgG antibodies to Red Cell antigens.

*Note: Detailed explanations of these 2 methodologies can be found in Module 3 of the ECHO Training Guide.*

# Specimen Requirements

1. EDTA whole blood in 7ml Pink Top tube is specimen of choice.
2. Minimum tube size is 12 x 75 mm.
3. Serum with no additive may be used for Antibody testing.
4. Samples must be at 18°C to 30°C prior to testing.
5. Samples are centrifuged prior to testing - 5 to 10 minutes at 3000 to 3600 RPM.
6. Minimum packed RBC volume in sample tube: 250 µl
7. Minimum plasma or serum volume for Antibody Screen: 500 µl
8. Minimum plasma or serum volume for Antibody ID Assay: 1000 µl
9. If Plasma or Serum is removed from primary tube and added to an empty sample tube, the minimum specimen volumes change as follows:
10. For Antibody Screen: 750 µl
11. For Antibody ID: 1.5 ml
12. **Limitations**:
13. Clotted specimens CANNOT be used for Hemagglutination (Group assay) testing, which uses CMT strips and liquid reagents.
14. Specimens exhibiting strong Cold Agglutinin reactivity may react as a clotted sample and therefore should not be tested on the Echo *(See "Prewarm Tube" procedure in Blood Bank Procedure Manual).*
15. Specimens exhibiting excessive Hemolysis, Icterus, or Lipemia should NOT BE tested on the Echo (refer to section 7.2 of ECHO Operator Manual for more detailed information).
16. Certain blood sample factors have a high likelihood of causing a "No Type Determined" (NTD) interpretation. These include serological factors due to the inheritance of weakly expressed gene products by certain diseases, such as Leukemia, recent transfusion of ABO/Rh-different RBCs, or due to the patient's age (missing or weakened antigen or antibody). NTD results can also occur due to interference from certain conditions such as elevated lipid, bilirubin, free plasma hemoglobin, clots, or aggregates. Always compare questionable results with patient history as well as past and present diagnoses. Confirm questionable or discrepant results using Tube and/or Gel testing procedures. Send to UBS if inconsistent results persist.
17. Samples not tested within 24 hours need to be stored at 2-8 °C.
18. Donor segments from units of blood collected in FDA-approved citrate-based anticoagulant are acceptable for ABO/Rh Confirmation testing and Crossmatches.

Note: Two segments per tube are needed to provide enough sample volume for all testing.

**Reagents**

1. The Galileo Echo has several racks that are designated for liquid reagents. All liquid reagents are in vials with lot-numbered barcodes. The operator loads the vials into the Reagent Racks, which are then inserted into the ECHO in designated slots in the center loading bay (see Galileo ECHO Operator Manual, chapter 1, "Racks", for visual depiction of Reagent and Sample racks).
2. ECHO Anti-Sera and Reverse-Type reagents can be used for bench testing. Whenever reagent volumes get too low for use on the ECHO, transfer to bench for ongoing testing.
3. Stir Balls – in order to keep all Red Cell reagents properly suspended, each vial of Red Cell reagent must have a Stir-Ball inserted before being placed on the analyzer.
4. *If you accidentally touch a stir-ball or drop it on the counter or floor, it is contaminated and must be discarded*.
5. The ECHO software monitors volume and expiration for each reagent vial. This information can be easily viewed on the main screen by placing the cursor over a reagent location – a pop-up box will appear showing all details (refer to section 2 of Echo Training Guide for visual depiction of Main Screen Layout). There is no refrigerated section on the ECHO for any reagents. All reagents may remain on the analyzer until their respective expiration date.
6. For detailed information on specific reagent requirements and expirations, see the "Blood Bank Reagent Inserts" manual.
7. Liquid reagent loading and unloading:
8. Write the open date & time on each vial of reagent and initial.
9. Remove caps.
10. Put stir-balls in newly opened vials of red cell reagents.
11. Remove any foam or bubbles from vials.
12. Place vials in appropriate reagent rack with long barcode visible through opening on right side.
13. Rack may be placed in any available Reagent slot.
14. When the rack is properly loaded, the LED will remain lit.
15. Verify that barcode and reagent ID information displayed on monitor is correct for all reagents.
16. If reagent barcode cannot be read, the ECHO will display a pop-up box that will allow you to enter the reagent vial information (see chapter 7 of Galileo ECHO Operator Manual for detailed steps for manually entering a misread barcode).
17. Micro-well Strips are loaded in matched pairs into strip holders, which are then placed on strip trays and loaded on the analyzer in the right-most loading bay. *Note that the strips and strips-holders are "keyed" so that they fit together only one way. Similarly, the strip holders and the strip trays are "keyed" so that they fit together only one way (see chapter 7 of ECHO Operator Manual for details)*. The ECHO software monitors usage and expiration for each Micro-well strip, and the information can be viewed as noted in #3 above.
18. Coated Micro-Typing (CMT) strips use Hemagglutination for "Group" assays to detect and identify ABO and Rh RBC antigens and IgM antibodies. Each CMT strip has 8 micro-wells coated with porcine gelatin to block adsorption of RBCs and plasma proteins to the plastic.
19. Capture-R strips use Solid Phase Red Cell Adherence for "Screen" assays to detect and identify IgG RBC antibodies. There are two different types of Capture-R strips – Capture-R Ready Screen (3), which *detects* the presence of IgG antibodies, and Capture-R Ready ID, which is used to *identify* IgG antibodies. Each Capture-R strip has 8 micro wells coated with RBC membranes from separate Group-O donors (refer to Module 3 of Echo Training Guide for more detailed information about Capture-R strips).
20. Phosphate-Buffered Saline: The ECHO has a fluidics module on the left-hand side which holds a container for Phosphate-Buffered Saline ("PBS"), which is the primary System Liquid. PBS is used by the pipettors, the probe rinse station, and the washer. The PBS container has an internal volume sensor which will create an alert on the main monitor when the volume becomes low. PBS is prepared by adding a full bottle of Immucor "pHix" to a 20L container of commercially prepared, unbuffered saline, and then verifying the pH.
21. Pipette a small amount of the PBS into a glass tube and check pH using pH strips. The acceptable pH range for the prepared System Liquid is 6.9 to 7.2. Write the pH on the 20L container.
22. Expiration of PBS is 30 days after preparation. As with all reagents, write the open date, expiration date, and your initials on the 20L container.

### Daily Maintenance / Initialization

1. Dayshift will be responsible for all regularly scheduled maintenance and QC (see "ECHO Maintenance" procedure for more details).
2. Ensure all liquid reagents are of sufficient volume for the next 24 hours.
3. Do not discard any liquid reagent vials until the indicated expiration date. If the liquid level of a vial of reagent is too low for testing on the ECHO analyzer, SAVE the vial and transfer it to the bench for ongoing use until it expires or is empty.
4. Empty the waste container, which is next to the PBS container in the Fluidics Module.
5. The daily start-up includes an Initialization, which is called "Instrument QC" in the ECHO software. This is different from the Reagent QC, which is described below.

*Note: If the ECHO is shut off for any reason, a new Initialization will need to be performed prior to any testing. Reagent QC will still be good for 24 hours from when it was run.*

### Loading Samples and Ordering Tests

1. The Galileo Echo has several racks that are designated for patient specimen tubes. There are also several racks designated for Donor unit Confirmations. See chapter 7 of the Galileo ECHO Operator Manual for visual depictions of each of these racks. Both types of racks are loaded into the designated slots in the left-most loading bay of the analyzer. The slots are narrower than the reagent slots to prevent inserting the wrong kind of rack. The openings for the sample barcodes face to the left.
2. Reagent QC.
3. Immucor provides 4 levels of QC for daily testing.
4. *Levels 1, 2 and 3 are for Hemagglutination and Capture-R QC.*
5. *Level 4 is used only for Phenotype (E,e,C,c & K) QC.*
6. These tubes are spun down and treated as patient specimens. Each tube is barcoded. If QC results fall outside of expected parameters, you must resolve the problem and rerun the QC. If problems persist, contact technical support. *You will not be able to perform patient testing if QC results are outside of limits*. When all QC is complete, gently mix each QC sample tube and place in refrigerator.
7. Steps for loading and ordering tests:
8. Place sample tube in Sample rack with bar-code visible through opening on left.
9. Rack may be placed in any available Sample slot.
10. When the rack has been properly loaded, the LED will remain lit.
11. Verify that sample ID information is correct for all samples.
12. If sample barcode cannot be read, the ECHO will display a pop-up box that will allow you to enter the sample information. You may type this information manually or use the hand-held scanner linked to the instrument.
13. When all samples have been properly loaded and identified, enter the "Run" menu by clicking on the appropriate icon at the top of the display. The icon is yellow and resembles a person running.
14. A window will pop up with all available test options. Click on the option(s) you want to add. *Note that whatever option(s) you select, it will apply to all specimens you choose on the following pop-up window*.
15. After you have selected your test options, click the "Next" button in the lower-right portion of the window. The window will now display all samples, including QC specimens that have been loaded on the analyzer. You may select each specimen individually, by rack, or you may select "All". Click the "Next" button in the lower-right portion of the window when you are finished.
16. The window will again display all loaded samples and ask which ones you want to run as STAT. Select which ones you want to run STAT, or, if none, just select "Next" in the bottom-right portion of the window.
17. The next window will be either:
18. A window that gives you a button that says "Begin Tests", if there are enough QC'd reagents and strips for all requested tests, or
19. If there are insufficient QC'd reagents and/or strips, a pop-up window will tell you everything you need to load before it can process the requested tests. Load all additional resources, or go back and modify your requests, and then you will be able to select the "Begin Tests" option. You will not be able to run until all necessary resources are on board and all QC is current.
20. When all reagent and resource demands are satisfied, the final window you see will have a "Begin Tests" button. Touch or click on this button to begin test processing.
21. You may load additional samples, reagents and strips while the ECHO is in process, as long as there are open slots. Request tests as noted above and begin the added "Run" in the same manner noted above.
22. Led Indicator lights:
23. If any slot has a solid lit LED light, you may not add or remove any racks or trays to that slot.
24. If the slot LED light is off, you may add or remove the rack or tray.
25. If the slot LED light is flashing, there has been a loading or sampling error and a pop-up window will tell you what action is required to correct it.

#### Validate and Print Results

1. All ECHO interpretations must be reviewed by a technologist prior to reporting. Any discrepancy noted between the ECHO's final interpretation and the Tech's visual interpretation of a test result must be resolved. Use another test methodology (Tube or Gel) to resolve discrepancy. If discrepancy cannot be resolved using reagents and methods present at VVMC, collect additional specimens from patient and send to UBS (See Send-Out policy in Procedure Manual for more details).

*NOTE: DO NOT SEND OUT THE ORIGINAL SPECIMEN – RETAIN THE ORIGINAL SPECIMEN IN THE BLOOD BANK DEPT.*

1. All completed tests will automatically be displayed on the ECHO computer monitor. All reactions and interpretations must be checked visually. Touching or clicking on an image will enlarge it in a separate window. Any question marks or NTD results must be resolved.
2. The left-hand "Results" sub-menu will list every specimen and batch that is currently in the computer memory. Clicking on one will open that specimen's test results, or, clicking on a batch will open the test results for all specimens in that particular run.
3. Once you are satisfied with all results, Approve by doing one of the following:
4. Click the green checkmark icon in the "Results" sub-menu, or
5. Right-click on a batch or specimen, and then select "Approve" from the drop-down box.
6. Print the report by touching or clicking on the Printer icon at the top of the main menu. Any single result or batch run that is displayed on the monitor will then print out.

##### Entering results in Cerner

1. Using the ECHO printed report, enter patient results in Cerner.
2. Click on the "Result Entry" icon on the Cerner App Bar.
3. Enter the patient requisition number corresponding to the printed report from the ECHO.
4. The Echo tests for Anti-D using 2 different clones. If either of the Anti-D results are Positive, the positive result is entered into Cerner and the patient is considered to be Rh positive.
5. Initial the ECHO report and place in the bin labeled "Echo Results".

**References:**

1. Immucor Gamma, Galileo Echo Operator Manual, Version ECO-001-100;101 Norcross, GA, 2007
2. Immucor Gamma, Galileo Echo Training Guide, Version ECO-003-201, Norcross, GA, 2011
3. AABB, **American Association of Blood Banks Technical Manual**, 17th Edition, Bethesda, MD 2011
4. AABB, **Standards for Blood Banks and Transfusion Services**, 28th Edition, Bethesda, MD 2012

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