GALILEO ECHO STANDARD OPERATING PROCEDURE

PURPOSE

The Galileo Echo is an automated Blood Bank analyzer capable of performing testing on donor and patient samples. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red blood cell phenotyping.

PRINCIPLE

The Galileo Echo is designed to automate standard immunohematology assays and to operate as a walk-away system, meaning the Galileo Echo can be left to operate independently for periods of time. The Echo is a closed system and can only be used with specified ImmucorGamma products.

The Echo is a robotic instrument programmed to move micro-well strips, liquid reagent fluids, and blood sample fluids to different processing areas for a given assay in the correct sequence, such as the incubator, the micro-well washing station, the centrifuge, and the reader.

The Echo micro-well reader uses a CCD camera to capture an image of the micro-well. The software calculates a reaction value for each well based on a multi-feature image analysis. The well is then assigned a result and interpretation based on predefined criteria associated with the calculated reaction value. Some assay protocols require multiple test wells for a given blood sample interpretation, such as ABO and Rh (D) typing.

Two test methodologies are utilized in the Echo system.

1. Hemagglutination.
2. Solid phase technology.

The Echo uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the Galileo Echo.

GUIDELINES

1. Phosphate Buffered Saline has an optimal pH of 6.90-7.20 and is prepared by adding 1 bottle of pHix to 20L cube of isotonic unbuffered saline. Saline should not be used if pH is <6.50 or >7.50. Expiration should be dated 30 days after preparation.
2. The humidity indicator must be verified to be BLUE prior to using any strips. If humidity indicator has turned PINK, the strips must be discarded.
3. Reagents should be placed on the analyzer with the longer barcodes facing out toward the barcode reader.
4. Check reagent red cell vials for hemolysis or dark coloring; do not use if hemolysis or dark color is present.
5. Red cell vials must have a stir ball.
6. Indicator cells expire 24 hours after the addition of the stir ball, if a stir ball is accidently touched or dropped it must be discarded and a new stir ball used.
7. ~~Assure~~Ensure no bubbles are in the reagent vials, levels are adequate to facilitate daily testing or the next vial in use will be from the same lot, and vials will not expire at midnight. Antisera should be free from contamination with no visible turbidity.

SAMPLE REQUIREMENTS

The specimen of choice is a properly labeled EDTA vial.

1. Anticoagulated samples containing clots must not be used.
2. Samples obtained from tubes containing neutral get separators may produce falsely positive results and should therefore not be tested on the Galileo Echo.
3. Specimens exhibiting ≥ 1+ hemolysis, excessive lipemia or icterus should not be tested on the Galileo Echo.
4. At least 250ul of packed red blood cells need to be present in a sample tube to ensure the probe picks up red blood cells and not plasma for those assays that require red blood cells.
5. At least 500ul of plasma needs to present in a sample tube to ensure that the probe picks up plasma. Samples, being tested for red blood cell antibody identification, require approximately 1000ul of plasma.
6. Samples must be centrifuged for 5 to 10 minutes at 3000 to 3600 RPM prior to use on the instrument.
7. Specimen should be 18-30°C (room temperature) and less than 72hrs old.
8. Samples not tested within 24 hours must be stored at 2-8°C.

QUALITY CONTROL

1. Daily/weekly/monthly maintenance must be performed before daily QC.
2. The Echo must be initialized every 24 hours to ensure proper function, the analyzer will not operate if initialization is not performed within the specified time frame.
3. Daily QC requires WB corQC tubes 1, 2 and 3 to be performed once every 24 hrs on the Galileo Echo. The analyzer will not operate if QC has not been performed.
4. WB corQC manufactured by ImmucorGamma must be stored at 1-10C when not in use.
5. Do not use controls beyond expiration date.
6. Do not use leaking tubes.
7. Reagent red cells should not be used if the red blood cells darken, spontaneously clump, or if there is significant hemolysis. Slight hemolysis may occur with age.
8. The WB corQC tubes must be centrifuged prior to use to separate the red blood cells from the diluents. Tubes should be mixed ***gently*** prior to centrifugation.
9. To perform QC on Echo log on to the computer.
   a. Change ~~the~~all liquid reagents daily, opening a new vial of indicator cells prior to running QC. Two sets of liquid reagents are kept available for use on the Echo, each day the reagents will be alternated into use.
   b. Load QC vials into any sample rack with the barcode presented in open space of sample rack. Load the sample rack into sample bay of Echo.
   c. On the task bar at the top of the screen select the "Run a Test" button. From this menu select "~~GROUP~~DAILY QC"; click next, then click on "**SELECT ALL**".
   d. A window will open on the screen listing what strips need to be loaded. Strips must be oriented with barcodes facing out. The Echo will detect that the necessary materials are placed and a "**BEGIN TESTS**" icon will appear, select this icon to begin testing.
   e. ~~Once again select the "Run a Test" button. From this menu select "**SCREEN**", select next, click on "**SELECT ALL.**"~~

f. A window will open on the screen listing what strips need to be loaded. Strips must be oriented with barcodes facing out. The Echo will detect that the necessary materials are placed and a "**BEGIN TESTS**" icon will appear, select this icon to begin testing.

10. The Echo will perform the QC; if the results are incorrect the analyzer will flag invalid next to the level and no patient testing can be performed until QC is repeated and the correct results obtained. QC may be run separately for the Group or the Screen, instead of choosing DailyWBeQCQC choose the test that failed QC, the analyzer will know this is a QC run based on the sample barcodes. Record employee initials in the QC box on the Galileo Echo Maintenance Record once QC is acceptable.

PROCEDURE

SAMPLE LOADING

1. Barcoded patient sample will be inserted into a sample rack with barcode facing through opening on left of rack as to be visible to the barcode reader in the sample loading bay.
2. Insert the loaded sample rack in one of the available lanes of the sample loading bay (lane LED not illuminated).
3. Sample IDs not automatically read by the sample loading bay barcode scanner may be manually entered or scanned in using the hand-held scanner. The sample rack is removed from the sample loading bay the barcode from the sample tube is scanned or entered into the relevant field position.
4. WithOnce a specimen is loaded a tab will appear at the bottom of the screen which will say, "There are # worklist entries. Touch here to continue." Select the tab. All ordered tests will show up, tests may only be run by sample or in batches by type of test, i.e. only run groups together or screens together. Select all the ordered antibody screens and select next.
5. A supply screen will appear prompting for the loading of any missing reagent strips or reagents. The Galileo Echo will cycle the clips to detect that the necessary strips are loaded for test completion. Once this is completed click on **"BEGIN TEST"** to start the specimen processing.
6. When running DATs, Antibody Identification panels, Crossmatches or antigen typing tests will need to be ordered manually. On the task bar at the top of the screen select the "Run a Test" button.
7. Select the test(s) desired and select the "Next" button.
8. Another box will display and in the top left it will read **"SELECT SAMPLES"**. The accession numbers are displayed along with the rack # and position # of each loaded specimen. It will also indicate "patient". Select the sample(s) to test.
9. After selecting the "Next" button another box will appear allowing any or all samples to be designated as "Stat", select a sample if appropriate, and then click the "Next" button.
10. A supply screen will then pop up prompting the loading of any missing strips or reagents. After the supplies have been loaded click on the "Begin Test" button to start the specimen processing.
11. More specimens may be loaded if lane positions are available, or additional tests may be requested at any time on the samples already loaded.
12. Removing racks while the probe is accessing the tubes or vials results in damage to the probe and invalidated results. Only remove racks when the LED is NOT illuminated.
13. As specimens are processing the accession number will be displayed in a column on left of computer screen. It will have a **"?"** in front of ID number and will indicate **"Pending"** to the right of the accession number.

14. ABO, Rh (D) and antibody status will be displayed on completed specimens.
15. Once results are complete review them on the Echo Galileo computer screen. If ~~they look~~ results appear acceptable choose the button with the green check mark to approve the results.
16. Next select the red arrow button to export the results from the Echo to Cerner.
17. If a discrepant result exists, i.e. an ABO discrepancy, Rh Discrepancy or positive or inconclusive antibody screen, specimen results may be visualized on computer screen and will be printed for entry of completed work into Cerner. Record all investigations of discrepancies on the Echo print out or the Blood Bank Patient Worksheet, even if the discrepancy is solved by simply repeating testing at the bench.
18. If manual entry is not required a print-out is not necessary.
19. Hard copies of manually entered patient results or discrepancy investigations will be placed in ~~tray for patient work completed during the day.~~ the appropriate designated location for review.

VIEWING TEST RESULTS

1. Double-click the sample ID listed in the "**RESULTS PANEL**" to display the report for that sample.
2. Single-click (or press) the sample (or batch) ID in the "**RESULTS PANEL**" and then press the "**DISPLAY RESULTS**" button on the "**RESULTS BAR**" to display the report for that sample of batch.
3. Select "**PRINT**" to obtain a copy of the displayed test(s).
4. All assay reports display standard information- the Test name, Software version, Operator ID, Assay version, Batch number, Instrument ID, Profile name and Instrument name; as well as patient test results.

LIMITATIONS

1. The Galileo Echo must be switched on at least 30 minutes prior to the first assay being run to allow the incubator to warm up.
2. Immucor requires the use of phosphate-buffered saline prepared by adding pHix to commercially prepared, unbuffered saline. pHix is a concentrated solution of dissolved monopotassium and dipotassium salts. The addition of pHix to unbuffered saline, in the proper proportions, will bring the pH to an optimal range of 6.90-7.20.
3. Results can be adversely affected if the system liquid container is filled with anything other than PBS. Disconnecting the PBS supply bottle during operation will abort all tests in progress.
4. Specimens exhibiting strong Cold Agglutinin reactivity may react as a clotted sample and therefore should not be tested on the Echo.

Refer to Galileo Echo Operators manual for troubleshooting and detailed operation.

ATTACHMENTS N/A

REFERENCES Echo Galileo Operator Manual. 2007 ImmucorGamma