**TRAINING UPDATE**

| | | | |
|---|---|---|---|
| **Lab Location:** | SGMC and WAH | **Date Implemented:** | 10.27.2015 |
| **Department:** | Blood Bank | **Due Date:** | 11.15.2015 |

**DESCRIPTION OF PROCEDURE REVISION**

## Name of procedure:

Galileo Echo Testing Patient Specimens

## Description of change(s):

1. Added the requirement for the tech to verify the internal positive and negative control results that are built into the RS-3, Ready-ID, Extend I, and Extend II plates.
2. If an internal control fails for any reason, the tech **MUST** write a PI/variance report.

## Electronic Document Control System

**Document No.:** WAH.BB105[4]
**Title:** Galileo Echo Testing Patient Specimens
**Owner:** LESLIE BARRETT
**Status** INWORKS
**Effective Date:** 22-Nov-2015 **Next Review Date:**

Technical SOP

| | | |
|---|---|---|
| **Title** | **Galileo Echo Testing Patient Specimens** | |
| **Prepared by** | Stephanie Codina | Date: 5/9/2011 |
| **Owner** | Stephanie Codina | Date: 5/9/2011 |

| **Laboratory Approval** | **Local Effective Date:** | |
|---|---|---|
| **Print Name** | **Signature** | **Date** |
| *Refer to the electronic signature page for approval and approval dates.* | | |
| | | |
| | | |
| | | |

| **Review** | | |
|---|---|---|
| **Print Name** | **Signature** | **Date** |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## TABLE OF CONTENTS



## 1. TEST INFORMATION

| Assay | Method/Instrument | Local Code |
|---|---|---|
| ABO/Rh Typing | Echo/Hemagglutination | TS, ABR, ABC, CORDEV |
| Antibody Screen | Echo/Solid Phase Red Cell Adherence | TS or AS |
| Antibody Identification | Echo/Solid Phase Red Cell Adherence | N/A |
| Crossmatch | Echo/Solid Phase Red Cell Adherence | XMECHO |
| Antigen Typing | Echo/Hemagglutination | N/A |

| **Synonyms/Abbreviations** | |
|---|---|
| ABO/Rh Blood Grouping:<br>• Blood Group and Rh typing<br>• Forward and Reverse typing<br>• Rh factor, Rho type | Antibody Screen:<br>• Ab Screen<br>• Indirect Coombs |
| Antibody Identification:<br>• Panel<br>• ABID | Antigen Typing:<br>• Patient phenotyping<br>• Red cell phenotyping |

| **Department** |
|---|
| Blood Bank |

## 2. ANALYTICAL PRINCIPLE

The Galileo Echo is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation, and data management functions. The Galileo Echo is designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red cell phenotyping.

ABO typing is performed by the ECHO instrument by the hemagglutination method. The ABO blood group system of Landsteiner (1900) is used. The classification of blood groups A, B, O, and AB is based on the presence or absence of A and/or B antigens on the red blood cells and the presence or absence of anti-A and anti-B antibodies in the serum.

Rh (D) and antigen typing (C, c, E, e, and Kell) are also performed by hemaggluintion methodology. Red blood cells are tested with antibodies directed towards the antigen being tested. Agglutination indicates the presence of the antigen on the test cells; no agglutination indicates the test cells lack the antigen being tested.

Antibody detection and identification procedures are performed by the ECHO instrument by the solid phase method based on the procedures of Plapp et al and Juji et al. Membranes of red cells have been bound and dried to the surfaces of polystyrene microfiltration strip wells. The membrane antigens are used to capture red cell-specific IgG antibodies from patient sera. After an automated wash procedure to remove any unbound IgG, indicator red cells coated with anti-IgG are added and centrifuged. Adherence is evidence of antibody presence.

The crossmatch tests use a modified capture procedure. The Capture-R Select (CRS) strips provide modified microwells for the immobilization of human erythrocytes for the detection of red cell antibodies. The wells of the CRS strips are coated with an immunologic agent to immobilize red cells to the microwell surface. Once the red cell immobilization has been performed, the assay can be applied in the same manner as other Capture tests.

## 3. SPECIMEN REQUIREMENTS

### 3.1 Patient Preparation

| Component | Special Notations |
|---|---|
| **Fasting/Special Diets** | None required. |
| **Specimen Collection and/or Timing** | None required. |
| **Special Collection Procedures** | N/A |
| **Other** | N/A |

### 3.2 Specimen Type & Handling

| Criteria | | | |
|---|---|---|---|
| **Type -Preferred**<br>**-Other Acceptable** | 10 mL purple top EDTA tube<br>5 mL purple top EDTA tube | | |
| **Collection Container** | Pink or lavender top EDTA tubes – diameter between 12 – 16 mm with maximum tube height of 100 mm. | | |
| **Volume - Optimum**<br>**- Minimum** | 10 mL whole blood<br>3.5 mL whole blood<br>1.5 mL whole blood for type and screen. An additional 1.0 mL of plasma for antibody identification is required. | | |
| **Transport Container and Temperature** | Ship in collection tube. Refrigerated 1-10°C. Do not freeze. | | |
| **Storage and Stability Requirements** | | ABO/Rh Testing | Antibody Screen |
| | Room Temperature: | 3 days | 24 hours |
| | Refrigerated: 1-10°C | 10 days | 10 days |
| | Frozen: -20°C or colder | Not Acceptable | Not Acceptable |
| **Timing Considerations** | N/A | | |

Form revised 10/31/02

| Criteria | | | | |
|---|---|---|---|---|
| **Unacceptable Specimens & Actions to Take** | 1) Specimens that are not properly labeled.<br>2) Specimens with any anticoagulant other than EDTA.<br>3) Whole blood in serum separator tube (SST).<br>4) Grossly hemolyzed, lipemic and/or icteric specimens.<br>5) Clotted specimens.<br>Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS. | | | |
| **Compromising Physical Characteristics** | **Condition** | **Slight** | **Moderate** | **Marked** |
| | **Hemolysis** | OK | Unacceptable | Unacceptable |
| | **Icterus** | OK | OK | Unacceptable |
| | **Lipemia** | OK | OK | Unacceptable |
| **Other Considerations** | None | | | |

## 4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

### 4.1 Reagent Summary

| Reagents | Supplier & Catalog Number |
|---|---|
| Anti-A, Series 1 | Immucor 6400 or equivalent; stockclerk 133748 |
| Anti-B, Series 3 | Immucor 6406 or equivalent; stockclerk 152328 |
| Anti-D, Series 4 | Immucor 6412 or equivalent, stockclerk 152332 |
| Anti-D, Series 5 | Immucor 6414 or equivalent, stockclerk 104164 |
| Monoclonal Control | Immucor 66089 or equivalent, stockclerk 135601 |
| Specimen Diluent | Immucor 66052 or equivalent, stockclerk 152329 |
| Referencells (A1 and B) | Immucor 2345 or equivalent, stockclerk 3092 |
| WBcorQC | Immucor 66090 or equivalent, stockclerk 152334 |
| DAT Positive Cells | Immucor 66122 or equivalent, stockclerk 152330 |
| Capture LISS | Immucor 6420 or equivalent, stockclerk 118835 |
| Capture-R Indicator Cells | Immucor 6428 or equivalent, stockclerk 141692 |
| CMT Plates | Immucor 89000 or equivalent, stockclerk 152338 |
| Capture-R Ready Screen (3) Plates | Immucor 66813 or equivalent, stockclerk 134185 |

| | |
|---|---|
| Capture-R Ready-ID Plates, Capture-R Select Plates, Capture-R Ready-ID Extend I, Capture-R Ready-ID Extend II | Immucor 66214 or equivalent, stockclerk 140735<br>Immucor 6446 or equivalent, stockclerk 135016<br>Immucor 6454 or equivalent, stockclerk140736<br>Immucor 6456 or equivalent, stockclerk 140737 |
| RelyOn | Immucor 65525 or equivalent, stockclerk 139855 |
| pHix Buffer Solution | Immucor 5070 or equivalent, stockclerk 152340 |
| Isotonic Saline, Certified blood bank saline | Fisher 535-435 or equivalent, stockclerk 37684 |
| Water, Reagent Grade, Type I | Fisher 23249589 or equivalent, stockclerk 23011 |

## 4.2 Reagent Preparation and Storage

**NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.**
**Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.**

| Reagent | Preparation and Storage/Stability |
|---|---|
| Blood Grouping Reagents: anti-A, anti-B, anti-D4, anti-D5, monoclonal control, specimen diluent | Store at 1-10°C. Stable until manufacturer's expiration date. Bring to room temperature (18-30°C) approximately 30 minutes before use.<br>NOTE: Reagents should be refrigerated at 1-10°C when not in use. |
| Referencells (A1 and B) | Store at 1-10°C. Stable until manufacturer's expiration date. Bring to room temperature (18-30°C) approximately 30 minutes before use. Add one Stir Ball to each vial prior to use.<br>NOTE: Once opened, reagents should be refrigerated at 1-10°C. when not in use. |
| WB corQC | Store at 1-10°C. Stable until manufacturer's expiration date. Bring to room temperature (18-30°) approximately 30 minutes before use. Centrifuge for 5-10 min. at 3000 – 3600 before use. Return to refrigerator (1-10°C) once sampling is completed. |
| DAT Positive Cells | Store at 1-10°C. Stable until manufacturer's expiration date. Bring to room temperature (18-30°C) approximately 30 minutes before use. Add one Stir Ball to each vial prior to use.<br>NOTE: Once opened, reagents should be refrigerated at 1-10°C. when not in use. This reagent is good for 72 hours on the Echo or 7 days from the time that the stirring ball is added if refrigerated when not in use. |

| | |
|---|---|
| Capture LISS | Store at 1-10°C. Stable until manufacturer's expiration date. Bring to room temperature (18-30°C) approximately 30 minutes before use.<br>NOTE: Once opened, reagents should be refrigerated at 1-10°C. when not in use. |
| Capture-R Indicator Cells | Store at 1-10°C. . Stable until manufacturer's expiration date until opened. Bring to room temperature (18-30°C) approximately 30 minutes before use. Add one Stir Ball to each vial prior to use. Discard 24 hours from the time that the stirring ball is added. |
| CMT Plates | Store at 1-30°C. Stable until manufacturer's expiration date or 60 days after opened, whichever is sooner. Use only if desiccant is present in bag and indicator is blue in color.<br>NOTE: Strips removed from pouches must be used within 72 hrs. |
| Capture-R Ready Screen (3) Plates, Capture-R Ready-ID Plates, Capture-R Select Plates, Capture-R Ready-ID Extend I, Capture-R Ready-ID Extend II | Store at 1-30°C. Stable until manufacturer's expiration date. Use only if desiccant is present in bag and indicator is blue in color.<br>NOTE: Strips removed from pouches must be used within 8 hrs. |
| RelyOn | Two tablets are to be added to 1 liter of deionized water immediately before the disinfecting procedure. **The powder is corrosive and should not be handled without wearing protective clothing and gloves.** Stable for 30 days. |
| pHix Buffer Solution | Add 1 bottle (200 ml.) pHix to one cube of isotonic saline (20L). Store at ambient temperature (18-30°C) for a maximum of 30 days. pH of buffered saline should be 6.5 – 7.5 as tested with a pH strip.<br>Record lot#, expiration date and pH on Phix Log. |

NOTE: Vials of reagents that have remained continuously on the Echo for 72 hours should be discarded and replaced with fresh vials. In addition, vials of reagents that are removed from the Echo when not in use and refrigerated can be used up to their expiration dates. (This does not apply to Indicator cells which expire 24 hours after stir ball is added and DAT Positive Control Cells which must be discarded 7 days after the stir ball is added.)

## 5. CALIBRATORS/STANDARDS

### 5.1 Calibrators/Standards Used

Not Applicable.

### 5.2 Calibrator Preparation and Storage

Not Applicable.

### 5.3 Calibration Procedure

The Echo's microplate reader uses CCD (charge-coupled device) cameras to capture an image of the microplate from underneath. The Echo software calculates a reaction value for each well based on a multi-feature image analysis. The Echo then assigns a result and interpretation to the wells 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. The performance of the daily QC and internal checks help to ensure accurate testing results.

## 6. QUALITY CONTROL

### 6.1 Controls Used

| Controls | Supplier & Catalog Number |
|---|---|
| WBcorQC | Immucor, Cat.#66090. SC# 152334. |

**CAUTION: All materials containing human blood components should be considered as potentially infectious.**

### 6.2 Control Preparation and Storage

**NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation, hemolysis, or discoloration.**

| **Control** | **Monoclonal Control & Echo WB corQC & DAT Positive Control Cell** |
|---|---|
| **Preparation** | Ready to use as supplied. Add 1 stir ball to the DAT Positive Control Cell prior to use. |
| **Storage** | Store at 2-8°C. Bring to room temperature (18-30°C) prior to use. |

| | |
|---|---|
| **Stability** | Echo WB corQC is stable until manufacturer's expiration date if stored in the refrigerator when not in use. Monoclonal Control and DAT Positive Control Cell must be discarded after 72 hours on the Echo if used continuously. If stored at 1-10°C when not in use, the monoclonal control can be used until the manufacturer's expiration date and the DAT positive control cell must be discarded 7 days after the stir ball has been added. |

## 6.3 Frequency

Control testing must be performed on each day of use. The Galileo Echo will automatically require QC when a new lot number of reagent is placed on the instrument.

Control material should perform as expected. Results should be compared to those obtained on previous runs. Control results must be reviewed prior to release of result, document review with initial and date.

## 6.4 Tolerance Limits

- Control material should perform as expected. Refer to procedure, "Galileo Echo Daily Reagent Quality Control" for additional information.
- The results of the forward typing and reverse grouping must agree. If a discrepancy is found, notify the supervisor or designee; take corrective action and document on worksheet.

| IF | THEN |
|---|---|
| If the test procedure is thought to be satisfactory | • Check quality control material.<br>• Date quality control material put into use.<br>• Review quality control values.<br>• Check for control/red cell material contamination.<br>• Check Reagent dating. |
| If conditions are thought to be reproducible | • Verify proper technique used<br>• Verify centrifuge set at appropriate speed.<br>• Verify if washer functioning properly |

## 6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results.

## 6.6 Documentation

WB corQC results will be printed and maintained in a binder. Results will be reviewed, initialed, and dated by the technologist confirming that results are as expected.

## 7. EQUIPMENT and SUPPLIES

### 7.1 Assay Platform

Immucor Galileo Echo System

### 7.2 Equipment

| Equipment | Supplier |
|---|---|
| Galileo Echo with computer | Immucor |
| Printer | Immucor |
| UPS dedicated power supply | Immucor |

### 7.3 Supplies

| Materials | Supplier |
|---|---|
| 70% Isopropyl alcohol (for equipment cleaning – NO BLEACH ALLOWED on the Echo's) | Stock Clerk #9014960 |
| Stir Balls | Immucor SC# 139112 |

## 8. PROCEDURE

**NOTE: For all procedures involving the handling of specimens, lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.**

**The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.**

### 8.1 Instrument Set-up Protocol

| Step | Action |
|---|---|
| 1 | Verify specimen labeling per procedure, "Sample Specifications for Blood Bank Testing." Apply a barcode label per procedure if needed. |
| 2 | Perform a history check per procedure, "Patient History Check." Patient history check can be performed at any point before the test is complete. |
| 3 | All specimens must be spun at 3000-3600 rpm for 5-10 minutes before being tested. All caps on specimens and reagents must be removed after centrifugation as the instrument cannot pierce caps. |
| 4 | The instrument will not process patient specimens unless reagent QC has been performed in the previous 24 hours. A new lot of reagent will also cause the instrument to require complete QC testing prior to testing patient samples. |

| Step | Action |
|---|---|
| 5 | Load reagents onto the Echo.<br>  <br>A. Reagent racks are indicated by the symbol:<br>B. Ensure all reagents are at room temperature (18-30°C).<br>C. Remove and discard the reagent droppers and specimen caps. Inspect the reagent vial for bubbles.<br>a. Remove bubbles with a transfer pipette, but do not discard the pipette filled with reagent and bubbles.<br>b. Hold the transfer pipette at an angle until the bubbles float to the top.<br>c. Slowly expel the reagent back into the vial, stopping before the bubbles are dispensed.<br>D. Ensure each red cell reagent contains a stirball. Do not add additional stir balls to reagents which already have one.<br>E. Place the reagents into the reagent racks with the barcodes facing the right side of the rack.<br>F. If the reagent has two bar-codes, use the bar-code that **does not** have "ABS" above it.<br>G. Ensure the barcode scanner is on before adding reagents to the instrument. Failure to do this may cause an assertion error which will require restarting the Echo.<br>H. Slide the reagent racks into the reagent loading bay one at a time.<br>a. Verify the barcodes have been read.<br>b. Rescan unread reagent barcodes using one of the following methods:<br>i. Rescan the reagent using the handheld barcode scanner.<br>1. Remove the rack with the unread barcodes after the **Reagents** window has been displayed.<br>2. Scan the missing unread barcode into the relevant field of the **Reagents** window with the hand-held scanner.<br>3. Reinsert the reagent rack into the correct lane of the reagent loading bay.<br>4. Press the **Close** button of the **Reagents** window.<br>ii. Enter the barcode manually.<br>1. Remove the rack with the unread barcode after the **Reagents** window has been displayed.<br>2. Type the missing unread barcode information into the relevant field of the **Reagents** window using the keyboard and reinsert the rack into the correct lane. Double entry of data is required.<br>3. Reinsert the reagent rack into the correct lane of the reagent loading by.<br>4. Press the **Close** button of the **Reagents** window. |

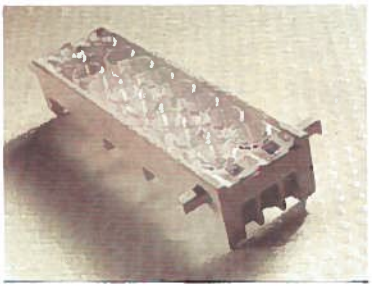
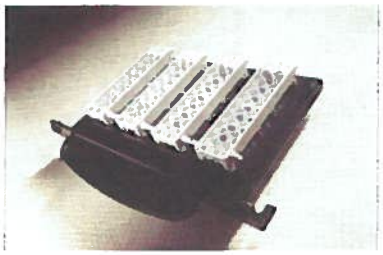
## 8.2 Test Run

| Step | Action |
|---|---|
| 1 | Load the samples onto the Echo.<br>A. Uncap the sample tubes.<br>B. Position the sample tubes in the appropriate rack and press them fully down to bottom of rack.<br>a. Place normal patient tubes in the sample rack:  <br>b. Place donor segments in the donor rack:  <br>C. Ensure sample barcode labels on sample tubes can be seen through the gap on the left of the sample rack.<br>D. Slide sample racks into sample loading bay one at a time.<br>E. Verify all barcodes have been scanned successfully. Successfully scanned barcodes appear in the tool tips of the **Samples** area of the **Instrument Map**.<br>F. Rescan unread sample barcodes by handheld barcode scanner or enter by manual entry.<br>a. To rescan with handheld barcode scanner:<br>i. Remove rack with unread barcodes after **Samples** window is displayed.<br>ii. Scan the missing unread barcodes into relevant field of the **Samples** window with hand-held scanner and reinsert rack into the correct lane. Double entry of data is required.<br>iii. Reinsert the sample rack into the correct lane of sample loading bay.<br>iv. Press the **Close** button of the **Samples** window.<br>b. To enter barcode manually:<br>i. Remove rack with unread barcodes after **Samples** window is displayed.<br>ii. Type the missing unread barcode information into relevant field of the **Samples** window using the keyboard and reinsert rack into the correct lane. Double entry of data is required.<br>iii. Reinsert the sample rack into the correct lane of sample loading bay.<br>iv. Press the **Close** button of the **Samples** window. |

| Step | Action |
|---|---|
| 2 | Order the assays that are not interfaced with the LIS.<br>A. Press the **Run Test Wizard** button on the **Tool Bar** to display the **Select tests** window.<br>  <br>B. Select the necessary assays from the **Select tests** window and then press **Next**. The **Select samples** window is then displayed.<br>C. Select the necessary samples from the **Select samples** window and then press **Next**. The **STAT tests** and **Priorities** window will only then be displayed if configured. Designate the necessary samples as stat or prioritize a list samples as appropriate. If the **STAT tests** and **Priorities** windows are not configured, then the **Supplies** window will be displayed.<br>D. Add the necessary supplies for the scheduled assays, as indicated on the **Supplies** window, according to the steps outlined in this SOP. As necessary supplies are added, items listed on the **Supplies** window will be eliminated. When all supplies are on the instrument, the **Next** button becomes available. Press the **Next** button. The **Confirm test** window is displayed.<br>E. NOTE: The **Crossmatch setup** window is displayed only if the **Crossmatch** assay is selected on the **Select tests** window. Donor samples are assigned to patient samples in this window for testing<br>F. **An immediate spin crossmatch must be performed in addition to an IgG crossmatch to rule out ABO incompatibility.** Refer to procedure, "Crossmatch." |

| Step | Action |
|---|---|
| 3 | Remove the micro-well strips from the foil packaging.<br>A. Remove the micro-well strips from the foil pouch. The strip wells are sealed in a foil pouch with a desiccant and humidity indicator. The strip wells should **not** be used if the humidity indicator shows the presence of moisture by turning from blue to pink.<br>B. The humidity indicator is acceptable if the color of the circle is as blue or bluer than the rectangle.<br>  <br>C. The humidity indicator is **un**acceptable if the color of the circle is lighter blue than the rectangle or pink in color.<br>  |

Form revised 10/31/02

| Step | Action |
|---|---|
| 4 | Load the micro-well strips onto the Echo.<br>A. Insert a pair of micro-well strips of the same type and lot number, or a balance strip along with a single strip of any kind and lot number, into a strip holder.<br>  <br>B. Each strip has a barcode on one end:<br>a. Place the strip in the strip holder by placing the barcode end of the strip in the winged end of the strip holder. "Barcode to Wings."<br>  <br>b. Place the strip holder onto a strip tray. "Wings to Wings."<br>  <br>c. Insert the strip tray into the strip loading bay.<br>d. Verify that all barcodes are read.<br>e. Rescan unread strip barcodes by handheld barcode scanner.<br>i. Open the **Strips** window via the **pull-down** menu.<br>ii. Scan the white frame barcode, from which the relevant strip was retrieved, into the relevant field (indicating the position of the unread strip barcode) of the **Strips** window with hand-held scanner. Double entry of data is required.<br>iii. Enter the strip expiration date as prompted.<br>iv. Press the **Close** button of the **Strips** window |

| Step | Action |
|---|---|
| 5 | Review the information on the **Confirm test** window and the press the **Begin Tests** button to start the assay(s). |
| 6 | Start the run.<br>A. Select the "Run" button (running man) on the Tool Bar.<br>B. Select the test(s) desired.<br>C. On the next screen select the specimens to be tested.<br>D. On the next screen select any specimen that needs to be run "stat."<br>E. Load all necessary reagents and strips as instructed.<br>F. Select "Begin Test" when all strips and reagents have been recognized by the instrument. Progress of tests may be monitored in the Progress Bar in the lower left of the screen.<br>G. Select the Worklist button on the Tool Bar or touch the Worklist comment above the Status Bar at the bottom of the screen to initiate reflexed antibody identification testing ordered by the instrument following a positive antibody screen result. (If indicated testing is no longer needed or will not be done due to lack of specimen, cancel the reflexed test from the Worklist screen.) |

## 8.3 Review Results

| Step | Action |
|---|---|
| 1 | View test results by one of the following methods.<br>A. Double-click on the sample ID listed in the **Results Panel** to display the report for that sample.<br>B. Single-click (or press) the sample (or batch) Id in the **Results Panel** and the press the **Display Results** button on the **Results Bar** to display the report for that sample or batch. |

| Step | Action |
|---|---|
| 2 | Review the results and take appropriate action, if indicated.<br>A. Visually verify the interpretation of all reactions. Verify that all red cell reagents contain stirballs if all wells of an antibody screen or antibody identification test are positive.<br>B. Verify the internal assay control results that are embedded into the RS-3, ReadyID, Extend I and Extend II strips. The purpose of these controls is to verify that the wash was sufficient and the indicator cells have not been neutralized.<br>a. DO NOT report results if the controls do not yield valid results.<br>b. Document each control failure on a PI/variance form. Be sure to include corrective action and patient impact. All PI/variance forms regarding failure of the internal control must be reviewed by the Technical Supervisor.<br>C. Recentrifuge and repeat any "NTD" (No Type Determined) result for ABO/Rh typing and any ABO/Rh results that yield reaction strengths <2+.<br>a. Repeat testing may be performed on the Echo or by manual tube testing.<br>b. Weak reactions in the series 5 anti-D well do not need to be repeated if the strength of the reaction is the series 4 anti-D well is ≥2+ in strength.<br>D. Edit equivocal (?) reactions, as indicated.<br>a. Negative and 1+ positive results are differentiated by examining the edges of the red cell button.<br>i. Negative results will have clearly defined edges.<br>ii. 1+ reactions will have slightly fuzzy edges.<br>iii. Refer to addendum 1 for additional information.<br>iv. Use built in positive and negative controls as a visual guide where available.<br>b. For ABO/Rh testing, examine the forward and reverse ABO reactions as well as the appearance of the red cell button prior to interpreting. It is acceptable to interpret equivocal ABO/Rh results. Testing can be repeated in tube when questions about interpretations exist.<br>c. For antibody screen tests, edit all equivocal results to 1+ positive or document as "?" and perform an antibody identification procedure. The antibody screen results can entered as "inconclusive" and interpreted following review of the antibody panel. |

| Step | Action |
|---|---|
| 2 Cont | d. To edit results:<br>i. Select the **Edit Results** button  on the **Results Bar.**<br>ii. Modify the result in the **Edit** Results window by first selecting the well result in question (by highlighting with the blue line) and then selecting the new grade from the **Revised** Grade drop-down list.<br>iii. Enter the comment "Visual Inspection" into the **Comment for revised grade** field.<br>iv. Press the **Close** button to close and save. The edit symbol appears next to the edited results in the **Results Panel.**<br>E. Manually test specimens that yield "invalid" results. This indicates that insufficient specimen volume was available. The Echo will not release partial antibody screen or identification results. |
| 3 | Approve test results.<br>A. Select the result or batch from the **Results Panel.**<br>B. Press the **Approve Results**  button on the **Results Bar** to approve the selected results.<br>a. An information balloon message will temporarily display a message indicating the result was approved.<br>b. The approve symbol will appear next to the approved results in the **Results Panel.**<br>Note: Click the **Approve Results** button a second time to "unapproved" results that were erroneously approved. |
| 4 | Export the test results to the LIS.<br>A. Select the result or batch from the **Results Panel.**<br>B. Press the **Export Results**  button on the **Results Bar** to export results. The export symbol will appear next to the exported results in the **Results Panel.** |
| 5 | Print the results of all positive antibody screens and results that will not be entered via interface. This includes:<br>A. Results that cannot be interfaced (antigen typing, antibody identification, and crossmatch).<br>B. Results that won't cross the interface (results for which a QA failure is generated because of ABO discrepancy or discrepancy between current and historical results).<br>C. Results that will be entered manually due to Sunquest or interface downtime.<br>These results will be entered manually and require a second tech to verify data entry. |

| Step | Action |
|---|---|
| 6 | Review the interfaced results in Sunquest using the instructions in appendix A and appendix B. |

### 8.4 Remove Specimens

| Step | Action |
|---|---|
| 1 | Remove completed specimens from the Echo. Cap the specimens and place them in the appropriate rack for storage. |
| 2 | Remove and discard all strips used in the biohazardous waste container. **Do not** discard balance strips. Balance strips should be saved for reuse. |
| 3 | Log off of the Echo when patient testing is complete. |

### 8.5 Troubleshooting

| Step | Action |
|---|---|
| 1 | When you encounter an onscreen error or warning message, print the screen using the Print Screen key on the keyboard. There are various tools that can be used to clarify the cause of an error: Error Codes (see ECHO Operator's Manual, Chapter 13 for complete list of information messages, warning messages, error messages, and yes or no messages), Event Log Report, Instrument Log, Camera Report, Result File, and Test Event Log. The Event Log may be accessed through "Reports" in the top pull-down menu. Enter a date range, and select Errors and Warnings to minimize the number of items listed. See the ECHO Operator Manual Chapter 13 for detailed instructions. |
| 2 | If a clot is detected by the probe, a loud alarm will sound and the probe will remain suspended above the tube in question.<br>A. The operator will have 2 minutes to decide whether to "Continue Processing" if the probe is clean or a small droplet of blood is present.<br>a. The probe will move to the wash station for cleaning.<br>b. Processing will continue for all specimens except the specimen in which the clot was detected. The instrument will abort testing on the specimen in which the clot was detected.<br>B. If a clot is still hanging off of the tip of the probe, the operator should choose "Stop Processing" and all samples currently being processed must be retested. It will be necessary to shut down the ECHO, remove the instrument shroud, and manually clean the probe with PBS-saturated Kim-Wipes. |

| Step | Action |
|---|---|
| 3 | If the Echo is out of service for any reason:<br>A. Manual Capture will be used for antibody screen and antibody identification procedures.<br>B. Manual tube testing will be used for ABO, Rh, and antigen typing.<br>C. LISS tube methodology will be used for AHG crossmatching when the Galileo Echo is unavailable. |

## 9. CALCULATIONS

Not applicable

## 10. REPORTING RESULTS AND REPEAT CRITERIA

### 10.1 Interpretation of Data

| ABO/RH and Antigen Typing Test Performance | |
|---|---|
| | **Test Interpretation** |
| **Negative Test** | Absence of either macroscopic agglutination or hemolysis of the cell button. A negative test result indicates that the presence of the corresponding antigen or antibody is not demonstrable. |
| **Positive Test** | Presence of either macroscopic agglutination or hemolysis of the cell button at any tested phase. A positive test result may indicate the presence of the corresponding antigen or antibody.<br>NOTE: Agglutinates in microplate well are indicative of a positive reaction. Properly resuspended negative reactions will appear as a uniform cell suspension without agglutinates.<br>All positive reactions will be graded according to the criteria listed below by the Echo: |

**ABO/Rh Results**

| Reaction of Cells Tested With | | | | Reaction of Serum or Plasma Tested With | | Interpretation |
|---|---|---|---|---|---|---|
| Anti-A | Anti-B | Anti-D | Monoclonal Control | A1 Cell | B Cell | |
| 0 | 0 | 0 | 0 | + | + | O-negative |
| 0 | 0 | + | 0 | + | + | O-positive |
| + | 0 | 0 | 0 | 0 | + | A-negative |
| + | 0 | + | 0 | 0 | + | A-positive |
| 0 | + | 0 | 0 | + | 0 | B-negative |
| 0 | + | + | 0 | + | 0 | B-positive |
| + | + | 0 | 0 | 0 | 0 | AB-negative |
| + | + | + | 0 | 0 | 0 | AB-positive |
| Any Result | Any Result | Any Result | + (any strength) | Any Result | Any Result | Invalid |

Any reaction that is positive and <2+ in strength requires additional testing. For ABO, retest manually or refer to procedure "ABO Discrepancies." For Rh, perform "Weak D" testing.

| Antibody Screen Interpretation | |
|---|---|
| | **Test Interpretation** |
| **Negative Test** | • (Solid Phase) Button of Capture-R Ready Indicator Red Cells at the bottom of the well with no area of adherence.<br>• (Manual Tube Test) Absence of either macroscopic agglutination or hemolysis of the cell button |
| **Positive Test** | • (Solid Phase) Adherence of Capture-R Ready Indicator Cells to part or the entire reaction surface.<br>• (Manual Tube Test) Presence of either macroscopic agglutination or hemolysis of the cell button |
| **Internal Assay Control** | • The positive internal assay control (in the antibody screen and identification plates) must yield a positive result. The negative internal assay control (in the antibody identification plates) must yield a negative result.<br>• If the internal assay control fails,<br>o DO NOT report patient results<br>o Document the failure with corrective action and patient impact on a PI/variance. The PI/variance must be reviewed by the Technical Supervisor. |

The ECHO will grade ABO/Rh testing reactions in the same manner as that of manual testing results.

The ECHO will grade and score antibody screen and antibody identification reactions. Only equivocal reactions may be edited. WB corQC and positive test reactions may not be edited. A negative solid phase test shows a button of Capture-R Ready Indicator Red Cells at the bottom of the microwell with no area of adherence. A positive test shows adherence of Capture-R Ready Indicator Cells to part or the entire reaction surface with little or no button visible.

### 10.2 Rounding

Not applicable

### 10.3 Units of Measure

Not applicable

### 10.4 Clinically Reportable Range (CRR)

| IF the result is ... | THEN Report Antibody Screen as... |
|---|---|
| Negative | Negative |
| Positive | Positive and perform an antibody identification |

### 10.5 Repeat Criteria and Resulting

| IF the result is ... | THEN... |
|---|---|
| NTD | ABO/Rh testing will be repeated or performed manually. Discrepancies resolved before results are released into LIS System. |
| INVALID (solid phase antibody screen or identification) | If sufficient specimen remains, manual microtiter plate or tube testing will be performed. If not, additional specimen must be requested. |
| EQUIVOCAL (solid phase antibody screen or identification) | Result will be reviewed per criteria outlined in step 2 of the "Review Results" section of the procedure. |

## 11. EXPECTED VALUES

### 11.1 Reference Ranges

N/A

### 11.2 Critical Values

None Defined.

### 11.3 Priority 3 Limit(s)

None Defined.

## 12. CLINICAL SIGNIFICANCE

**ABO/Rh:**

The ABO system is the most important system in transfusion therapy. Normal individuals contain antibodies in their plasma directed against the ABO antigen(s) they lack. Transfusion of ABO incompatible blood can result in severe transfusion reaction or even death due to immediate intravascular hemolysis.

Along with A and B the Rho(D) antigen is also very important. Although individuals who lack the antigen do not necessarily have anti-D, the potential to develop it is great. Exposure to the D antigen may elicit the formation of the antibody in 50-75% of Rh negative individuals. This includes immunization by transfusion or pregnancy.

Antibodies of both the ABO and Rh systems are involved in Hemolytic Disease of the Newborn (HDN), but anti-Rho(D) is the most severe. In 1939 Levine and Stetson reported on a case of a woman who delivered a macerated fetus. This was the first case of HDN due to the newly discovered anti-D. Prenatal patients who type as Rh negative should be followed during the pregnancy to identify those individuals who may develop anti-D.

**Antibody Screen:**

Unexpected antibodies are found in the sera of 0.3-3% of donors and patients. Many antibodies are of clinical importance since they may cause decreased red cell survival and result in hemolytic transfusion reactions, hemolytic disease of the newborn or autoimmune hemolytic anemia. In vitro antibody detection (screening) tests are employed to reveal the presence of these antibodies in patient and donor sera/plasma. Selected red cells are incubated with test sera/plasma under conditions that will optimize antibody detection.

## 13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

| | |
|---|---|
| 1 | All reagents and controls are FDA approved for this assay. No modifications have been validated for this assay. |
| 2 | Sample tubes should be positioned in the appropriate rack so that tubes fit securely, with the barcode labels visible through the gap on the left of the sample rack. |
| 3 | Daily reagent quality control (WB corQC) is required prior to ordering assays. |
| 4 | Inspect all reagents and controls for presence of foam, as foam may cause the Liquid Level Detection feature to aspirate foam rather than reagent. |
| 5 | Failure to add stirballs to reagent red cell vials may result in invalid or incorrect results. |
| 6 | The system displays the volume remaining in each reagent vial. The volume is based on the full volume of the container (for new vials) or the remaining volume (if the vial was previously used on the Galileo Echo). If the actual volume is less than that displayed (e.g. if some accidental spillage of antiserum has occurred), you can use the software to measure the reduced volume. |
| 7 | Incorrectly placing a micro-well strip in a strip holder may cause damage to the pipetting system and other modules. |
| 8 | Contents of red blood cell donor unit segments can be tested on the Galileo Echo. Prepare donor segment samples as follows:<br>A. Remove segments from blood bags, cut them and dispense contents into a tube sized between 10 and 16 mm in diameter.<br>B. Label test tube with unit ID barcoded label taken from the correct blood bag.<br>C. Centrifuge the contents using a serofuge for 60 seconds prior to testing.<br>D. Insert test tube into Donor rack for testing on Galileo. |
| 9 | The Echo cannot be used to detect ABO incompatibility between donor and recipient. An immediate spin crossmatch must be performed in addition to an IgG crossmatch to rule out ABO incompatibility. |
| 10 | Testing for ABO or Rh typing only is generally not performed on the Echo. |
| 11 | PBS may be added and waste removed from the system while the Echo is operating. If the PBS or waste supply lines are disconnected from the fluidics module for any reason, the instrument must be reinitialized prior to use. |

## 14. LIMITATIONS OF METHOD

### 14.1 Analytical Measurement Range (AMR)

Not applicable

### 14.2 Precision

Verified during Validation

### 14.3 Interfering Substances

- Under certain conditions, presence of foreign or abnormal substances in the serum/plasma make the cells appear to be agglutinated (Wharton's jelly, high concentrations of fibrinogen or abnormal proteins, irregular globulin proportions).
- False results will be obtained when samples with a mixture of cell types are provided, such as when patients have been transfused with blood of a different ABO group or Rh type.
- Presence of atypical cold-reactive antibodies in the patient's serum/plasma may present a discrepancy between forward and back ABO grouping. Determination of the presence of such cold agglutinins will be helpful in resolving the discrepancy.
- ABO antibodies may also be weak in elderly patients or patients with hypogammaglobulinemia.

- Antibody Screen Limitation
  - Erroneous test results can occur from bacterial or chemical contamination of test material, inadequate incubation periods, improper centrifugation, inadequate washing or omission of test reagents or steps.
  - Overcentrifugation of the tests, following addition of the Indicator Cells, may result in falsely negative or doubtful positive reactions due to the collapse of the adherent indicator layer.
  - Undercentrifugation will lead to falsely positive results.
  - Addition of Indicator Cells in excessive amounts may cause false negatives or doubtful test reactions.
  - Addition of too few Indicator Cells may cause weak falsely positive results. Indicator Cells

**Note: For a detailed list of limitations, refer to the Capture-R Ready Screen package insert.**

### 14.4 Clinical Sensitivity/Specificity/Predictive Values

Examples of pure IgG4 subclass antibodies may not be detected by Capture-R Ready Indicator Cell reagent. Note, however, that pure IgG4 antibodies are very uncommon. Antibodies such as anti-M, -P1, -Lea and -Leb frequently react in tube hemagglutination tests at room temperature rather than at 37°C or AHG. Some of these antibodies may not

be detected in the Capture-R assays. These specificities are, however, regarded as insignificant in most clinical situations.
Some antibodies of presumed clinically significance that are wholly IgM in nature (i.e., anti-K or anti-E) may fail to react in Capture-R assays.
Some IgG antibodies have been shown to react poorly in solid phase red blood cell adherence assays. These include examples of antibodies to Bg, Kna, Csa, Yka, JMH, McCa, Ch, and Rg antigens respectively. Weak examples of clinically relevant antibodies are detected by an alternative technique. Passively acquired anti-D may fail to react even though the antibodies are detected by an alternative technique. NO ONE TEST METHOD IS CAPABLE OF DETECTING ALL ANTIBODIES.

## 15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

## 16. RELATED DOCUMENTS

SOP: Galileo Echo Daily Reagent Quality Control
SOP: Sample Specifications for Blood Bank Testing
SOP: Patient History Check
SOP: Confirmation of Patient's Blood Type (ABO Recheck)
SOP: Crossmatch
Current package inserts for Immucor Solid-Phase testing reagents and Blood Typing Reagents

## 17. REFERENCES

1. Fung, M.K., Grossman, B.J., Hillyer, C.D., and Westhoff, C.M. 2014. Technical Manual of the AABB, 18th ed. AABB Publishing, Bethesda, Maryland.

2. Standards for Blood Banks and Transfusion Services, 2014. AABB, 29th ed. AABB Publishing, Bethesda, Maryland.
3. Galileo Echo Operator Manual; Immucor, Norcross, GA.
4. Galileo Echo Training Manual; Immucor, Norcross, GA.
5. Package inserts for Immucor Solid-Phase testing reagents and Blood Typing Reagents; Immucor, Norcross, GA. Current Revisions.

## 18. REVISION HISTORY

| Version | Date | Section | Reason | Reviser | Approval |
|---|---|---|---|---|---|
| 000 | 1.17.2011 | 3.2 | Changed specimen stability from 7 to 10 days after consultation with manufacturer. | SCodina | NCacciabeve |
| 000 | 1.17.2011 | 8.5 | Listed methodology used in the event the Echo is unavailable for testing. | SCodina | NCacciabeve |
| 001 | 2.17.2012 | 3.2 and 8.2 | Deleted references to using microtainer tubes on the Echo | SCodina | NCacciabeve |
| | | 4.2 | Added 60 day expiration to opened CMT plates | | |
| | | 8.1 | Updated centrifuge settings from 3400 to 3000-3600 to be consistent with other Echo SOPs | | |
| | | 8.3 | Added visual inspection of all reactions; added check for stirballs if all reactions positive | | |
| | | 8.5 | Deleted reference to AHG crossmatch by manual capture | | |
| | | 13 | If the PBS or waste lines are disconnected from the fluidics module, the instrument must be initialized before use. | | |
| 002 | 1.29.2015 | | Removed references to DAT and Weak D from entire procedure; these tests were never validated for use on the Echo. | SCodina | NCacciabeve |
| | | Footer | Version # leading zero's dropped due to new EDCS in use as of 10/7/13 | LBarrett | NCacciabeve |
| 3 | 10.21.2015 | 8.3 | Added instructions to review the internal assay control and the steps that should be taken if this control fails to step 2. | SCodina | NCacciabeve |
| | | 10.1 | Added instructions for interpreting the internal assay control to the antibody screen interpretation. | | |

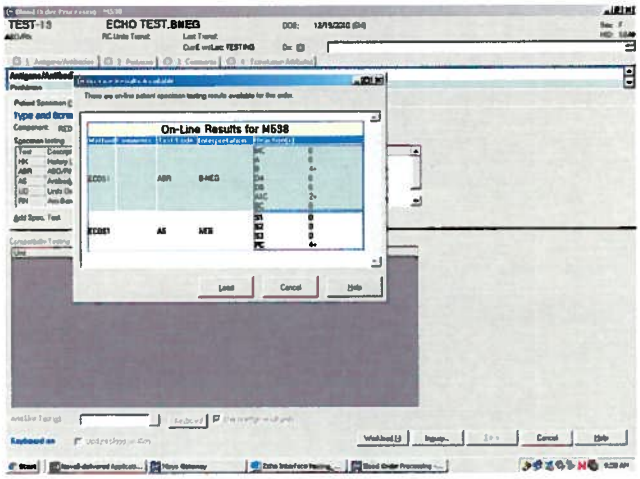
## 19. APPENDIX

Appendix A: LIS Entry of Patient Results Using the Echo Interface
Appendix B: LIS Entry of Unit Retype Results Using the Echo Interface

## 20. ADDENDA

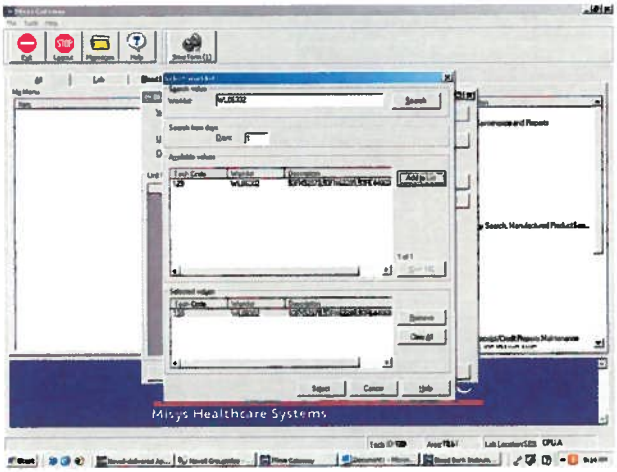
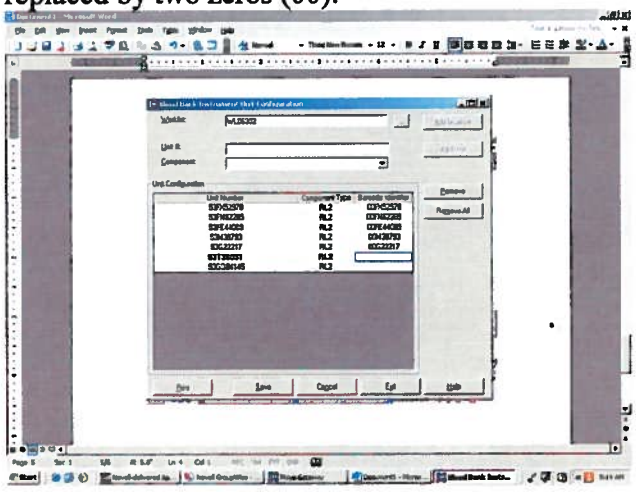
Addendum #1: Echo Antibody Screen and ID Interpretations
Addendum #2: NTD Interpretations on the Echo

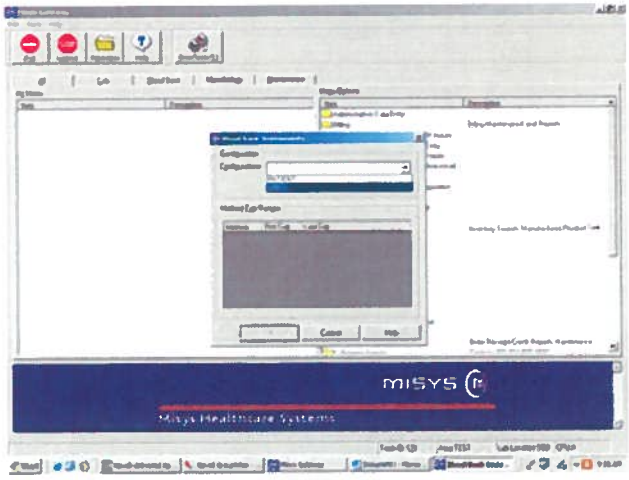
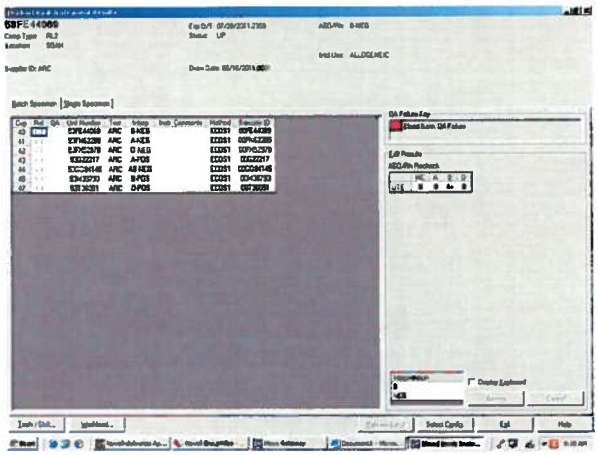
## Appendix A
## LIS Entry of Patient Results Using the Echo Interface

| Step | Action |
|---|---|
| 1 | Access Sunquest function "Blood Order Processing." |
| 2 | In the "Lookup By" box, select "Patient Name" from the dropdown menu. |
| 3 | In the "Value" prompt, type the first 3 letters of the patient's last name, then a comma, then the first 3 letters of the patient's first name. Click the "Search" button. |
| 4 | Highlight the correct patient encounter from the list of patient's that appear. Refer to procedure, "Patient History Check" for additional information. |
| 5 | Click the "Search All" button or the "Order Selection" tab. Select the correct specimen from the list of patient specimens. Note whether the patient needs an ABO confirmation specimen and order per procedure, "Confirmation of Patient's Blood Type (ABO Recheck)." |
| 6 | The interfaced results will appear.<br>A. Review the results for accuracy.<br>B. Click the "Load" button.<br>  |
| 7 | The results will file.<br>A. A QA failure will generate if the current results do not match the patient's historic results for ABO or Rh. An investigation must be performed before resulting.<br>B. A QA failure will generate if the ABO cannot be interpreted (no type detected). Results should be repeated using the Echo or manual tube prior to entering in the LIS. Click on the "Reject interface" (Reject ECOS1 ECOW1) button to remove results from the grid.<br>C. Enter results of other tests if applicable.<br>D. Click the "Save" button.<br>The results will file. |

Form revised 10/31/02

## Appendix B
## LIS Entry of Unit Retype Results Using the Echo Interface

| Step | Action |
|---|---|
| 1 | Access Sunquest function "Blood Bank Instrument Unit Configuration." |
| 2 | Type the worklist number in when prompted or click on the ellipses to search open worklists.<br>A. Click "Add to List."<br>B. Click "Select."<br>  |
| 3 | Type in the "Barcode Identifier" for each unit to be tested. The "Barcode Identifier" is identical to the unit number except the first two digits of the unit number (the number that identifies the collecting facility) are replaced by two zeros (00).<br>  |

| Step | Action |
|---|---|
| 4 | Access Sunquest function, "Blood Bank Instruments." |
| 5 | Select "Units" from the dropdown menu.<br>  |
| 6 | Save the results in Sunquest.<br>A. The results of the unit retypes will autofill.<br>B. Review the results.<br>C. Click on each unit result to be filed. A checkmark will appear in the "Rel" column when a unit has been selected.<br>D. Click on the "Release Batch" button when all unit results have been selected.<br>E. The message "Releasing Blood Bank Instrument Data" will show during the release.<br>F. Answer "OK" to the pop-up message.<br>  |
| 7 | Perform an online file cleanup (Sunquest roll-and-scroll function OFC) after each release of unit results. |

## Addendum #1 – Echo Antibody Screen and ID Interpretations

IMMUCOR GAMMA TechnicalCommunication

### Important Notification Regarding Echo Antibody Screen and ID Interpretations

This communication is to inform you that we are aware of some instances on the Echo where the instrument may generate a negative well interpretation for Capture-R® Ready-Screen® or Capture-R® Ready-ID® assays and subsequent visual interpretation of those reactions are weak positive or questionable (equivocal). We are recommending that you perform a visual verification of negative reactions before final release of those well results. Reaction images can be reviewed using the on-screen display.

Review of examples of this issue support that these are weak reactions near the threshold of detection and the reaction appearance is sometimes slightly atypical. Investigation indicates the cause is related to values assigned by the interpretation algorithm. Previous clinical evaluations of the Echo system with the current algorithm demonstrated that the system achieved a suitable degree of sensitivity for clinical use.

This issue impacts only the interpretation of reactions for the following Echo assays: Screen, Ready ID, Extend I, Extend II, and the screen portion of combination assays such as Group Screen.

Hemagglutination based assays, such as Group, RfxGroup, Pediatric, RfxPediatric, Donor, RfxDonor, Confirm,and RfxConfirm, and assays using Capture-R Select (Crossmatch, DAT and Weak D) are not involved and do not need further verification of negative reactions.

Immucor is aggressively pursuing refinements to the interpretation algorithm and anticipates that product improvements will be available first quarter of 2010.

To aid in review of these reactions, we have included a copy of the grading chart with this communication.

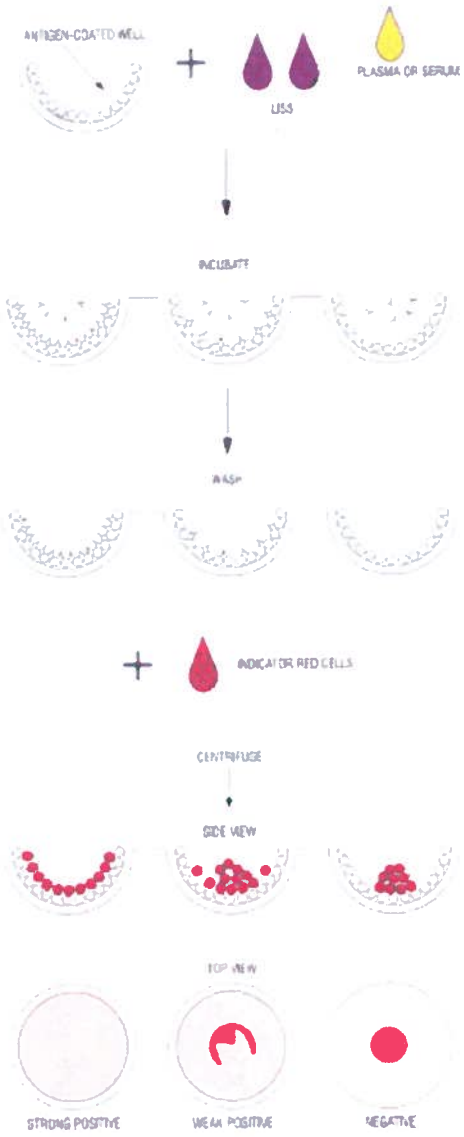
If you have questions about the information contained in this communication, please contact Technical Support at 800.492.2583.

www.immucor.com
3130 Gateway Drive
Norcross, GA 30091

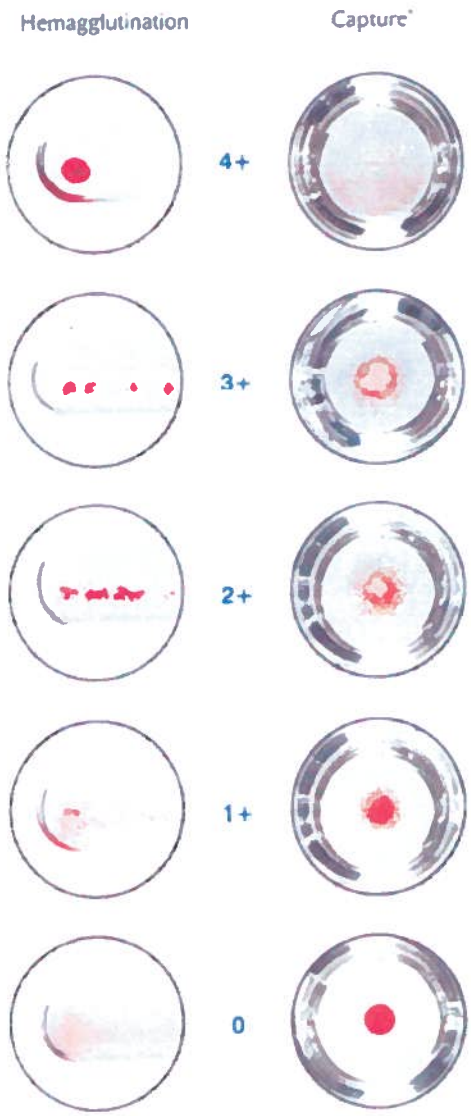
Technical Support
800 492 BLUD

CC-09-042-02
Issue Date: 25 NOV 2009
Page 1 of 2

## Capture Test Procedure




## Grading Chart






IMMUCOR GAMMA

Form revised 10.31.02

## Addendum #2: NTD Interpretations on the Echo

IMMUCOR GAMMA

**TechnicalCommunication**

### Investigation of Sporadic No Type Determined (NTD) Interpretations for Hemagglutination Assays on the Echo

We are currently investigating complaints of sporadic NTD interpretations due to unexpected equivocal or unexpected weak positive reactions for various test wells of Hemagglutination based assays on the Echo. Although this has been reported with various wells of the forward and reverse portions of the Group assay, in-house testing has reproduced the observation with only the Anti-A test well and Group B red blood cells. Upon visual inspection of the test well demonstrating the unexpected interpretation, the well will demonstrate infrequent clumps of red blood cells, surrounded by a background of unagglutinated cells. The second page of this communication provides examples of the reaction images.

Based on the presentation of the issue, we anticipate the issue could occur with the Group RfxGroup, Donor, Pediatric or Confirm assays. Most frequently, the expected reactions are observed on repeat testing. The frequency of occurrence is estimated as occasional.

You are being notified of this investigation so that you can evaluate your process and implement any additional precautions necessary. You should keep in mind the precautions and limitations published in the Echo Operator Manual regarding these assays:

*Forward only ABO-Rh testing has a higher risk of mistype due to the absence of the reverse type results. Hazardous mistypes may occur, such as an A sample being interpreted as a group AB, or an Rh (D) negative sample being interpreted as Rh (D) positive. For this reason, ABO-Rh results should always be compared to the patient or donor's history. Additionally, sample preparation and exclusion instructions contained in the relevant reagent direction circulars should be followed precisely. Specifically, anticoagulated samples containing clots must not be used. Samples obtained from tubes containing neutral gel separators and samples demonstrating a hemolysis grade of 3+ or greater must not be tested on the Echo.*

*Before decisions about medical treatment are made, or before red blood cell products are released for transfusion, ABO and Rh (D) test results should be verified. This verification can consist of a result comparison to a second current or historical ABO and Rh (D) test by the same or an alternative method or an immediate spin crossmatch. This limitation applies to all ABO-Rh assays, both with and without a reverse test.*

www.immucor.com
3130 Gateway Drive
Norcross, GA 30091

Technical Support
800.492.5100

CC-10-001-01
Issue Date: 22FEB2010