PROCEDURE
Corewell Health East - Fetal Cell Screening Using the FMH Rapid Screen Kit - Blood Bank

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle
This document will provide policies and instructions that will enable the Blood Bank staff to perform the fetal cell screen (FCS) test using the FMH RapidScreen kit that is provided by Immucor®.

A. Rh immunization in pregnancy may result if the mother produces antibodies that are directed at antigens present on the fetal red blood cells (RBCs) but absent on the maternal RBCs. Rh negative mothers delivering Rh positive infants are most susceptible. In most cases, Rh immunization can be prevented by the administration of Rh Immune Globulin (RhIG) within 72 hours of delivery. One standard 300 µg dose of RhIG is generally sufficient to prevent immunization when up to 30 mL of fetal whole blood (approximately 15 mL of RBCs) have entered the maternal circulation.

B. The Immucor FMH RapidScreen kit is a screening test used to detect the presence of D-positive fetal cells in D-negative mothers. In most cases the feto-maternal hemorrhage is not sufficient to cause a positive test, but in those cases where a significant volume of fetal blood has entered the maternal circulation, the test provides an indication that a quantitative test is required to determine whether the bleed was sufficient to warrant a larger dose of Rh Immune Globulin (RhIG) to the mother.

C. The FCS test is a qualitative test designed to detect a feto-maternal hemorrhage of an amount greater than that covered by the standard 300 µg dose of RhIG.

2. Responsibility
Personnel who have completed the competency requirements will perform this testing.

3. Definitions
A. BBIS: Blood Bank Information System
B. RhIG: Rh Immune Globulin
C. RhoGAM: Trade name for Rh Immune Globulin produced by Kedrion Biopharma Inc.
D. HyperRHO®: Trade name for Rh Immune Globulin produced by Grifols.
E. Rhophylac®: Trade name for Rh Immune Globulin by CSL Bering.

F. FCS: For the purposes of this document refers to the qualitative fetal cell screen that is performed in the Blood Bank.
G. FMH: Feto-maternal hemorrhage.
H. FMHA: The blood bank computer test code assigned to the final FMH report; completed after consideration of the FMH testing used for the final determination of total number of RhIG vials indicated for the patient.
I. FRBCG (LAB292): Refers to LIS test code for the RBC fetal assay; the quantitative feto-maternal hemorrhage test by flow cytometry laboratory, performed at Corewell-Royal Oak.
J. ACDEL (LAB474): Refers to LIS test code for the quantitative feto-maternal hemorrhage test by acid elution/Kleihauer-Betke stain. This test may be performed by the hematology departments at Royal Oak and Troy and in blood bank department at Dearborn.
K. Delivery: For the purposes of this document the term “delivery” applies to all pregnancies greater than 23 weeks gestation including full-term births and pregnancies that are terminated or interrupted for any reason.

4. Specimen

A. This procedure requires a blood specimen collected from the mother after delivery of all products of conception. It is best to wait at least an hour after delivery to allow any fetal RBCs to mix thoroughly in the maternal circulation, but the sample should be collected as soon as possible thereafter.
B. The preferred sample is a 6mL EDTA sample with affixed identifying label. Refer to Transfusion Medicine policy, Corewell Health East - Triaging And Identifying Acceptable Samples For Testing-Blood Bank - All Beaumont Hospitals.
C. Do not use grossly hemolyzed specimens for testing.
D. If a delay in testing occurs, the sample must be stored at 1 – 10 ° C for no longer than two days.
E. For additional information, refer to package insert for the FMH RapidScreen kit, provided by Immucor ®.

5. Reagent/Equipment Needed

A. Immucor® FMH RapidScreen Kit
   1. Anti-D Reagent: Contains monoclonal IgM anti-D antibodies from the human/murine heterohybridoma cell line GAMA401 grown in field culture and suitably diluted in bovine albumin to achieve the appropriate level of potency for the test procedure as described.
   2. Indicator cells: An approximate 0.5% suspension of group O RBCs obtained from a donor of the DcEe (R_2r) phenotype.
   3. Positive control: A 2 - 4% suspension of RBCs comprising approximately 99.4% group O, D-negative cells and approximately 0.6% group O, D-positive cells from a donor having heterozygous expression of the D antigen.
   4. Negative control: A 2 - 4% suspension of group O, D-negative RBCs.
   5. Storage and Handling of kit:
      a. Do not freeze, do not dilute, do not use beyond the expiration date.
      b. The FCS kit should be stored at 1 – 10°C when not in use.
      c. The indicator cells must be well-mixed before use. If marked hemolysis and/or darkening of the cells is present, the cells should not be used.
      d. The anti-D reagent should not be used if markedly turbid.
      e. All blood products should be treated as potentially infectious.
      f. The anti-D reagent contains 0.1% sodium azide as a preservative, which is classified as harmful.
B. Microscope
C. Timer
D. Centrifuge
E. 10 x 75 mm or 12 x 75 mm test tubes, 12 x 75 mm preferred
F. Transfer pipettes
G. Microscope slides

H. Isotonic saline, pH 6.5 – 7.5. Note that washing manually or using the automated cell washer is acceptable.

6. Quality Control

A. The positive and negative controls supplied in the kit should be tested in parallel with each batch of patient samples.
B. Appropriate reactivity of the positive control confirms the reactivity of the indicator cells and provides an indication that the test was performed correctly. The positive control must demonstrate a positive reaction (5 or more agglutinates per 5 low-powered fields), refer to the Interpretation section below.
C. The negative control confirms that the washing procedure removed all unbound anti-D reagent. The presence of agglutinates with the negative control suggests that the indicator cells are being agglutinated by unbound anti-D reagent (inadequate wash procedure). The negative control must demonstrate a negative reaction (4 or fewer agglutinates per 5 low-powered fields), refer to the Interpretation section below.

7. Procedure

A. Indications for Fetal Cell Screening
   1. The Blood Bank will assess RhIG candidacy if the mother's name appears on the Obstetrical Delivery List or if a physician orders a Rh Immune Globulin (RhIG) Evaluation.
   2. The Fetal Screen may only be performed on a sample from an Rh-negative mother after the delivery of an Rh-positive neonate greater than 23 weeks gestation. Note the following:
      a. The mother must be Rh-negative, and the neonate must be Rh positive in order to perform the Fetal Screen. If the Rh of the mother or neonate is weak D/partial D, unknown, or undetermined then the Fetal Screen test may not be performed; a quantitative fetal maternal hemorrhage testing should be performed in these cases using one of the following test codes.
         1) Fetal Cells by Flow Cytometry; LAB292
         2) Fetal Cells by Kleihauer Betke; LAB474
      b. It is not necessary to perform the Fetal Screen test if quantitative fetal maternal hemorrhage testing has already been performed after delivery; e.g., the Fetal Cells by Flow Cytometry test was performed after delivery because it was ordered by the physician. The quantitative Fetal RBC test results may be used to assess RhIG candidacy in this case.

B. Performance of the Fetal Screen
   1. Label four test tubes to identify the following:
      a. Positive control
      b. Negative control
      c. Maternal cell suspension (label with patient's name)
      d. Maternal Fetal Cell Screen test; label with patient's name and "FCS," for example.
   2. Prepare a 2 - 4% suspension of the well-mixed maternal whole blood in isotonic saline in the applicable test tube that was labeled in the previous step.
   3. Add 1 drop of anti-D reagent to the test tubes corresponding to the patient's FCS test, the positive control, and the negative control.
   4. Transfer 1 drop of the 2 - 4% maternal cell suspension to the tube labeled for the patient's FCS test.
   5. Add 1 drop of the positive control to the correspondingly labeled tube.
   6. Add 1 drop of the negative control to the correspondingly labeled tube.
   7. Mix well and incubate for 5 (± 1) minutes at room temperature (18°C - 30°C).
   8. Wash the RBCs 4 times (if using 12 x 75mm test tubes) or 6 times (if using 10 x 75mm test tubes).
   9. The RBCs may be washed using the automated cell washer or washed manually.
   10. Decant completely between washes and after the last wash.
   11. Resuspend the RBCs thoroughly when adding saline for the next wash.

12. Add 1 drop of indicator cells to the dry cell button obtained after washing to the patient's FCS test, positive control, and negative control. Mix each tube well by gently shaking. The indicator cells should be resuspended before use. Centrifuge immediately for the calibrated immediate-spin settings of the centrifuge.
13. Resuspend the RBC button and transfer a drop to a microscope slide.
14. Examine 5 low-power fields (approximately 100x magnification) microscopically for mixed-field agglutination. Determine the number of mixed-field agglutinates observed in the 5 fields. Results should be interpreted immediately upon completion of the test. Refer to Results/Interpretation section below.

8. Results/Interpretation

A. Positive Test: After examining 5 low-power fields, if 5 or more agglutinates of RBCs are observed the test should be interpreted as positive. This indicates the presence of Rh-positive fetal RBCs in possibly significant numbers in the maternal circulation. A quantitative test (FRBCG or ACDEL) is indicated to determine whether additional vials of RhIG are needed to prevent immunization. Refer to Transfusion Medicine procedure, Corewell Health East - Rh Immune Globulin Evaluation - Blood Bank - All Beaumont Hospitals.

B. Negative Test: After examining 5 low-power fields, if 4 or fewer clumps of agglutinated RBCs are observed the test should be interpreted as negative. This indicates that a large feto-maternal hemorrhage did not occur. Refer to Transfusion Medicine procedure, Corewell Health East - Rh Immune Globulin Evaluation - Blood Bank - All Beaumont Hospitals for further information on interpretation of the Rh Immune Globulin dosage and resulting.

C. Results are recorded in the BBIS following Transfusion Medicine procedures - SafeTrace (Blood Bank) Application .

9. Limitations

A. For correct interpretation of the FCS test, the test must be performed only on a sample from an Rh-negative mother after the recent delivery of an Rh-positive newborn.

B. If the neonatal RBCs possess a weak D or partial D antigen, the test may not detect a feto-maternal hemorrhage exceeding 30 mL of whole blood. A Fetal RBC Assay or acid elution by Kleihauer Betke must be performed in this case. Refer to transfusion medicine procedure, Corewell Health East - Rh Immune Globulin Evaluation - Blood Bank - All Beaumont Hospitals.

C. In some cases, maternal RBCs that are weak D or partial D positive are inadvertently tested because Corewell Health does not routinely perform weak D testing of maternal samples. A strongly positive FCS test may result if the mother is weak D or partial D positive. If this is suspected (as with all positive FCS tests) then a quantitative fetal RBC test is indicated. The maternal Rh should not be interpreted as weak D or partial D positive based on a strongly positive FCS test alone. For additional information refer to Transfusion Medicine procedures, Corewell Health East - Resolution of ABO and Rh Discrepancies - Blood Bank - All Beaumont Hospitals and Corewell Health East - Weak D Testing - All Beaumont Hospitals.

D. A strongly positive FCS test provides no information about the extent of feto-maternal hemorrhage.

E. If the neonate is Rh negative, a negative FCS result is expected regardless of the volume of feto-maternal hemorrhage. Fetal cell screening should not be performed in these instances.

F. In cases of ABO incompatibility between mother and child, the maternal ABO antibodies may destroy any fetal RBCs in the maternal circulation before testing. This is true for any method of detecting fetal RBCs in maternal circulation.

G. False-positive results may occur if the washing procedure is inadequate, or if the maternal RBCs have a positive direct antiglobulin test (DAT) due to an autoantibody capable of reacting with the indicator cells.

10. Revisions

Corewell Health reserves the right to alter, amend, modify, or eliminate this document at any time without prior written notice.

11. References

A. Package insert for the RBC Fetal Assay Rapid Screen, Immucor ® Insert code 3047-3, revision Date 03/2017.
B. College of American Pathologists, Transfusion Medicine Checklist, current edition.
C. AABB, Technical Manual, current edition.
D. AABB, Standards for Blood Banks and Transfusion Services, current edition.

12. Procedure Development and Approval

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13. Keywords

Not Set