Transfusion Medicine Quality Manual: Detection of Fetomaternal Hemorrhage

1.0 Policy Statements

1.1 All Regional Health Authorities shall develop and implement policies, processes and procedures that comply with Provincial Blood Coordinating Program policy to ensure that possible fetomaternal hemorrhages are detected.

1.2 Detection and quantification of FMH shall be completed for:

1.2.1 The assessment of fetal anemia in the event of FMH attributable to trauma or other pathology during pregnancy.

1.2.2 The prevention of Rh(D) sensitization of RH(D) negative mothers.

1.3 All potential candidates for Rh Immune globulin (RhIg) therapy shall be appropriately screened.

1.3.1 All potential candidates for RhIg shall have their Rh type and antibody screen completed.

1.3.2 A Kleihauer-Betke quantitative test shall be performed on all positive qualitative screening tests for RhD positive fetal red cells in maternal circulation.

1.4 RhIg should be administered to each Rh negative woman not known to be immunized to the D antigen, in the following situations:

1.4.1 At 28 weeks gestation;

1.4.2 Following delivery of an Rh positive neonate (including weak D positive or Rh unknown);

1.4.3 Following spontaneous or therapeutic abortion;

1.4.4 Following amniocentesis; and

1.4.5 Following any procedure or event known to be associated with increased risk of Rh immunization due to fetomaternal hemorrhage.

1.5 RhIg should be administered within 72 hours of delivery or other possible immunizing event.

1.5.1 RhIg may be given up to 28 days after delivery.

1.6 A test shall be performed to detect a fetomaternal hemorrhage of an amount greater than that covered by the standard 300 microgram does of RhIg. If a fetal bleed is detected, an appropriate dose of RhIg shall be given according to the manufacturer's recommendations.

1.7 Kleihauer-Betke test shall be used to detect a fetomaternal hemorrhage in RhD positive mothers (quantitative tests only detect RhD positive RBCs, not fetal RBCs).

1.8 Stained Kleihauer-Betke slides shall be read within 24 hours of staining.

1.9 Positive and negative controls shall be set up each time a qualitative or quantitative test for fetal red cells in maternal circulation is performed.

1.10 RHAs may have a qualitative screening test for RhD positive fetal red cells in maternal circulation; however in the event that that qualitative test is positive, a quantitative test must be available to measure the volume of fetal red cells in maternal circulation.

2.0 Linkages

Issuing Blood Components and Blood Products
http://www.health.gov.nl.ca/health/bloodservices/pdf/issuing_blood_components_ver_2.pdf

Patient History Check
http://www.health.gov.nl.ca/health/bloodservices/pdf/patient_history_check.pdf

Patient Identification and Specimen Labeling
http://www.health.gov.nl.ca/health/bloodservices/pdf/patient_id_and_specimen_labeling.pdf

Policy for Consent or Refusal to Administration of Blood Components and Blood Products
http://www.health.gov.nl.ca/health/bloodservices/pdf/informed_consent_blood_components.pdf

Policy for Patient Notification of Transfusion of Blood Components and Blood Products
http://www.health.gov.nl.ca/health/bloodservices/pdf/patient_notification.pdf

Preparation of Red Cell Suspensions
http://www.health.gov.nl.ca/health/bloodservices/pdf/preparation_of_red_cell_suspensions.pdf

Quality Control of Reagents and Antisera NL2012-043 Version 1
http://www.health.gov.nl.ca/health/bloodservices/pdf/quality_control_of_reagents_and_antisera_ver1.pdf

3.0 Scope

3.1 All Transfusion Medicine Laboratory Technologists

4.0 General Information

4.1 Normal adult blood contains less than 1.0% of fetal-type hemoglobin.

4.2 Qualitative screening tests for RhD positive fetal cells in maternal circulation can exhibit false positive results due to improper incubation times, temperature, centrifugation, or examination.

4.3 In cases of ABO incompatibility between mother and child, the mother's natural ABO antibodies may destroy any fetal cells in the maternal blood specimen before testing is performed.

4.4 A positive qualitative screening test for fetal red cells in maternal circulation result does not of itself provide evidence that an increased dose of RhIg is required. It indicates that a larger-than-normal FMH may have occurred. A quantitative procedure is required to determine the volume of the bleed (Kleihauer-Betke test).

4.5 If the infant's red cells possess a weak D antigen or partial D antigen, a qualitative test may not detect a FMH exceeding 30 mL of whole blood. Test based on fetal hemoglobin is recommended (Kleihauer-Betke test).

4.6 If maternal cells have a positive direct anti-globulin test, a false positive qualitative screening test may occur.

4.7 False positive Kleihauer-Betke test may occur:

4.7.1 Hematological disorders in adults may produce increased levels of fetal-type cells;

4.7.2 Lymphocytes may take up stain in varying degrees and can be mistaken for fetal cells.

5.0 Process

5.1 Quality Control

FETALSCREEN™ II

5.1.1 Positive and negative controls are included in the FETALSCREEN™ II kit.

FMS RapidScreen

5.1.2 Positive and negative controls are included in the FMH RapidScreen kit.

Kleihauer-Betke

5.1.3 Positive and negative controls are prepared in the laboratory. The controls are assayed in the same manner as the patient sample.

5.1.3.1 Positive control is prepared from 1 part cord blood and 9 parts normal adult male blood.

5.1.3.2 Negative control is prepared from normal adult male blood.

5.2 Procedure (NA)

5.3 Guidelines

5.3.1 Do not use grossly hemolyzed specimens for qualitative screening tests for FMH.

5.3.2 A qualitative screening test for RhD positive fetal cells in maternal circulation shall not be performed on obstetrical patients whose fetus:

5.3.2.1 are Rh negative; or

5.3.2.2 does not have a determined Rh typing.

The test only detects Rh positive cells in maternal circulation.

5.3.3 Cord blood is not acceptable for Kleihauer-Betke test.

5.3.4 Store sample for Kleihauer-Betke at 2-4°C until it can be tested.

5.3.5 Sample must be tested within 24 hours of collection.

5.4 Materials

5.4.1 Quantitative screening test for fetal red cells in maternal circulation such as:

5.4.1.1 FETAL CELL STAIN KIT (Kleihauer-Betke test)

5.4.2 Qualitative screening test for RhD positive fetal red cells in maternal circulation such as:

5.4.2.1 FMH Rapid Screen; or

5.4.2.2 FETALSCREEN™ II

6.0 Acronyms

EDTA	Ethylenediamine tetracetic acid (anticoagulant)
FMH	Fetomaternal hemorrhage
RhIg	Rh Immnue Globulin

7.0 Definitions

FETALSCREEN™ II	a qualitative test for the detection of D-positive red blood cells in the circulation of a D-negative mother.
Fetomaternal hemorrhage	the entry of fetal blood into the maternal circulation before or during delivery.
FMH RapidScreen	a qualitative test for the detection of D-positive red blood cells in the circulation of a D-negative mother.
Kleihauer-Betke test	the most widely used confirmatory test for quantifying FMH

8.0 Records Management

8.1 The recipient transfusion data file shall be retained 50 years.

8.2 All transfusion records in the recipient's medical chart, including pre-transfusion serological tests results and worksheets for identification of atypical antibodies shall be retained in accordance with health care facility's retention policy for medical records.

8.3 Quality control of blood components, blood products, reagents and equipment shall be retained for 5 years.

8.4 Records of blood components inspection prior to release must be kept for a minimum of 5 years.

9.0 Key Words

Kleihauer-Betke, Rh negative, fetomaternal hemorrhage, RhIg, FMH RapidScreen, FETALSCREEN™ II, FETAL CELL STAIN KIT

10.0 Supporting Documents

10.1 Process Flow/Algorithm (NA)

10.2 Tables/Charts

RhIg Dosage

Fetal/ Maternal RBC Ratio	Volume of Fetal Bleed	Vials of RhIg Indicated (WinRho 300 micrograms)
0 – 0.0045	0-30 mL	1
0.0046 – 0.0090	30-60 mL	2
0.0091 – 0.0135	60-90 mL	3
0.0136 – 0.0180	90-120 mL	4
0.0181 – 0.0225	120-150 mL	5

References

Canadian Society for Transfusion Medicine. (2011). CSTM standards for hospital transfusion service. Version 3. Ottawa: Author.

Canadian Standards Association. (2015).Blood and blood components, Z902-15. Toronto, ON: Author.

Immucor. (2015). FMH RapidScreen: Instructions for use. Norcross, GA: Author

Ortho Clinical Diagnostics. (2009). FETALSCREEN™ II: Instructions for use. Raritan, NJ: Author.

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