PROCEDURE

Title: ~~Transfusion Reaction Investigation~~ Fetal Membrane Rupture

Procedure #: 2015BLOODBANK56

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/4/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-5-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 12/20/2012

Review of procedure every two years

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

Policy Name: **Department:** **Blood Bank-Lab**
Detection of Excessive Fetal-Maternal Hemorrhage using the Rosetting Technique

Departmental Review: **Policy #:**

INITIATE DATE **DATE REVIEWED/REVISED** **PAGE 1 of 4**
12/20/2012

PRINCIPLE:

A single dose of Rh-Immune Globulin is ordinarily sufficient to prevent immunization when a volume of fetal D-positive red blood cells not exceeding 15mL (equivalent to 30mL of whole blood) leaks into the maternal circulation. Occasionally, a fetal-maternal hemorrhage can exceed this volume, in which case multiple doses of Rh-Immune Globulin may be needed to afford the required protection. The rosette procedure is a qualitative procedure for the detection of D+ fetal red blood cells in the maternal circulation.

When the red blood cell sample of a D-negative mother are incubated with Anti-D reagent at room temperature for 5 minutes any D+ fetal cells that may be present become coated with anti-D. The D-positive indicator cells added after washing form rosettes around any coated fetal D+ red blood cells to form readily detected agglutinates. In most cases the fetal-maternal hemorrhage is not sufficient to cause a positive test

POLICY

No special preparation of the patient is required before specimen collection. Blood should be drawn from the mother by an approved technique, preferably with anticoagulant. Grossly hemolyzed specimens are unacceptable for testing.

It is best to wait for an hour after delivery of all products of conception before drawing the blood sample, in order to allow any fetal blood to mix thoroughly in the maternal circulation.

If not tested immediately, the sample should be stored at 2° - 8°C. Storage limits are dependent on the manner of collection and storage conditions, but testing should be carried out as soon as possible, in order to assure that an appropriate dose of Rh-Immune Globulin can be administered within 72 hrs of delivery.

REAGENTS

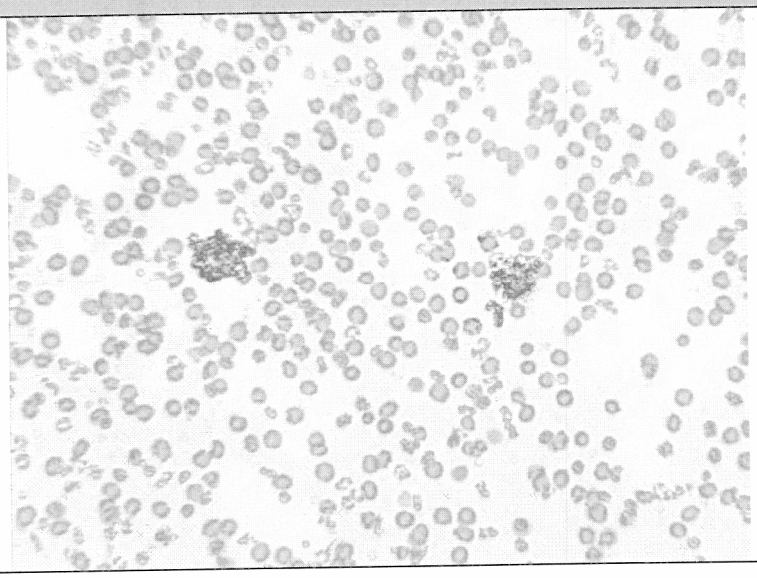
FMH RapidScreen Kit containing:

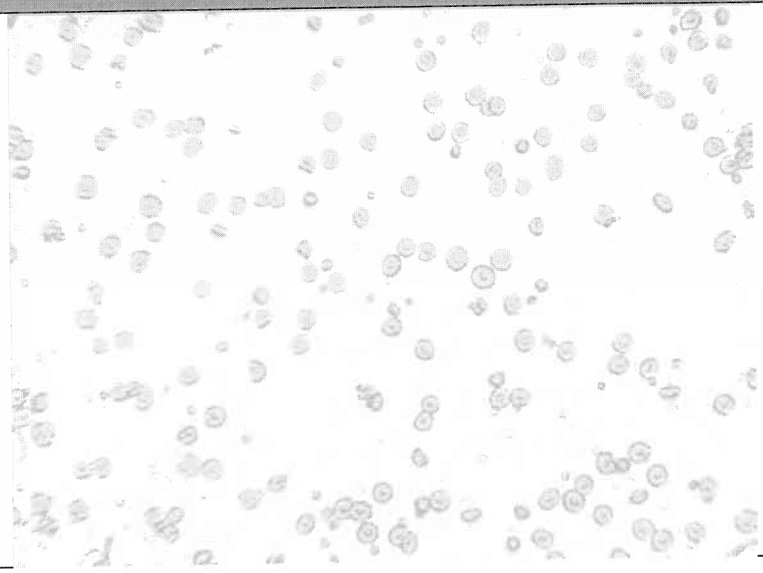
1. **Anti-D Reagent**: Monoclonal IgM anti-D antibodies in bovine albumin diluent containing 0.1% sodium azide as a preservative.
2. **Indicator Cells**: Approximate 0.5% suspension of group O red blood cells, DcEe (R_2r) phenotype.
3. **Positive Control**: A 2-4% suspension of red blood cells of approximately 99.4% D-negative cells and approximately 0.6% D-positive cells
4. **Negative Control**: A 2-4% suspension of group O D-negative red blood cells.
5. Isotonic Saline

QUALITY CONTROL

The reagents comprising this test kit should be tested with the controls supplied each time a patient blood is tested, as described in the procedure.

FMH RapidScreen





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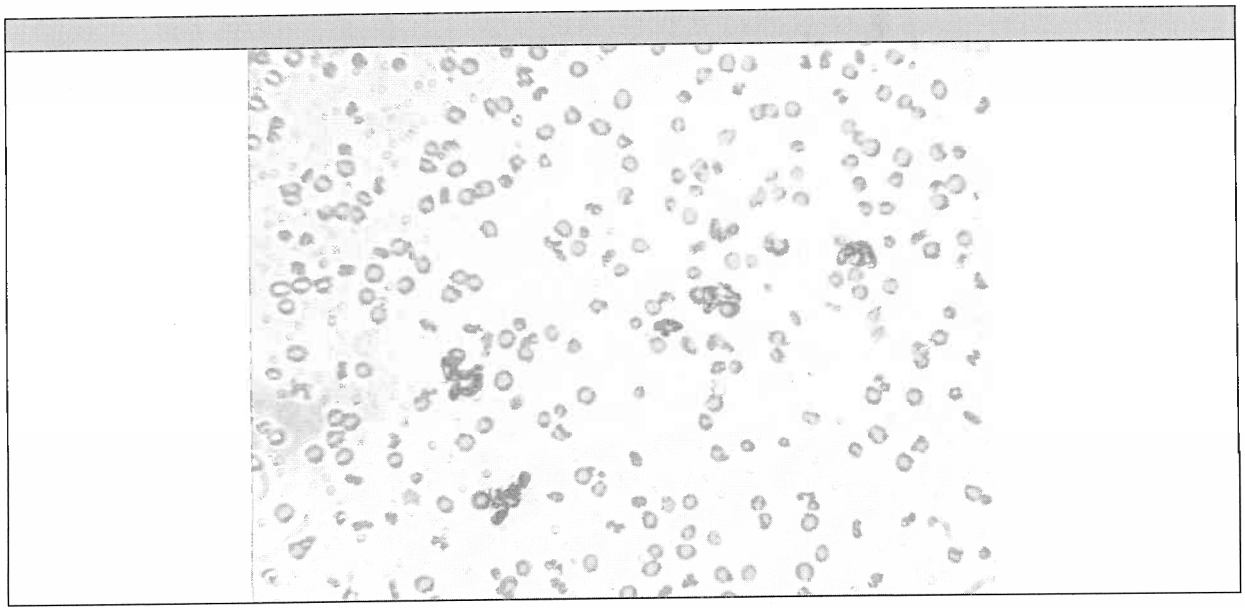
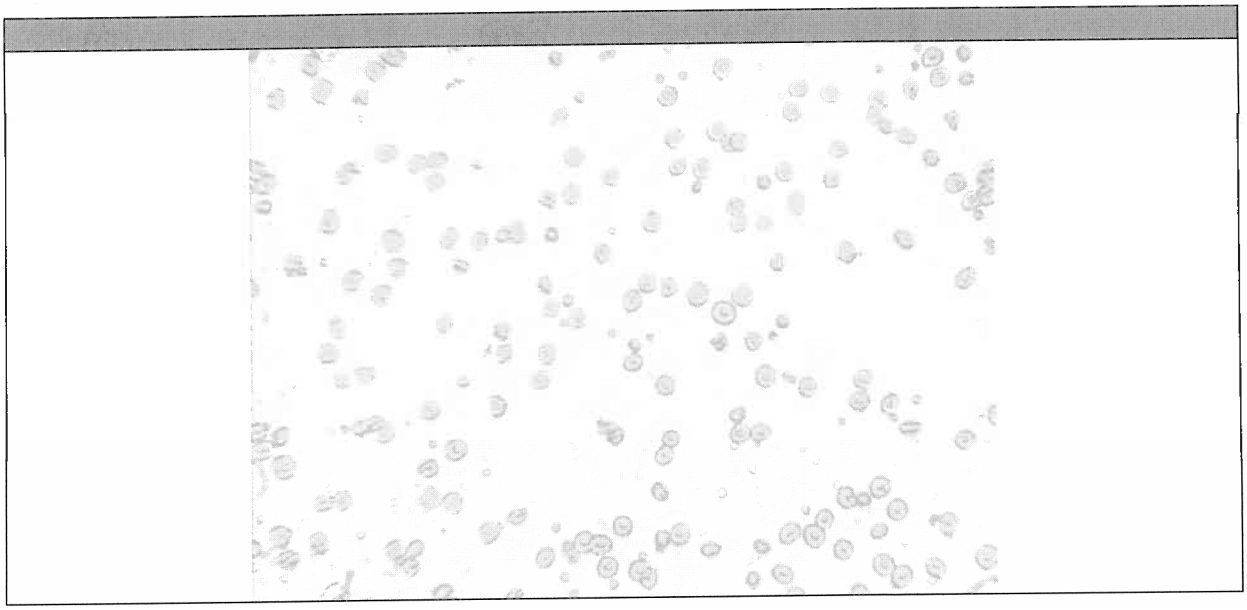
The following are typical examples of positive and negative test results for both the Fetal Bleed Screening Test and the FMH RapidScreen. These images are for reference only and individual results may not appear identical to the images below. Images below are viewed greater than 100x magnification to show detail. Results should be viewed at approximately 100x magnification which typically is performed using a 10x objective lens with a 10x ocular lens.

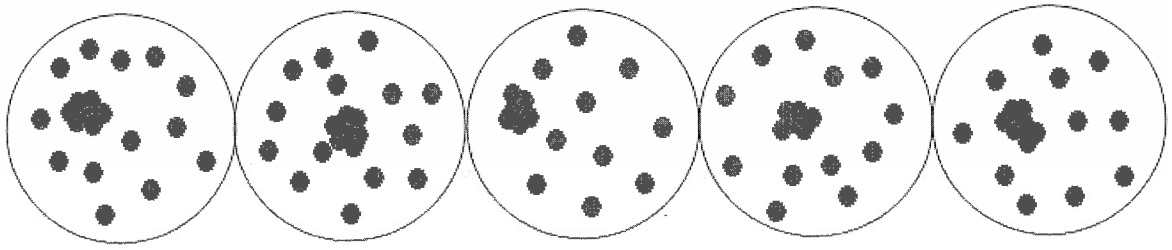




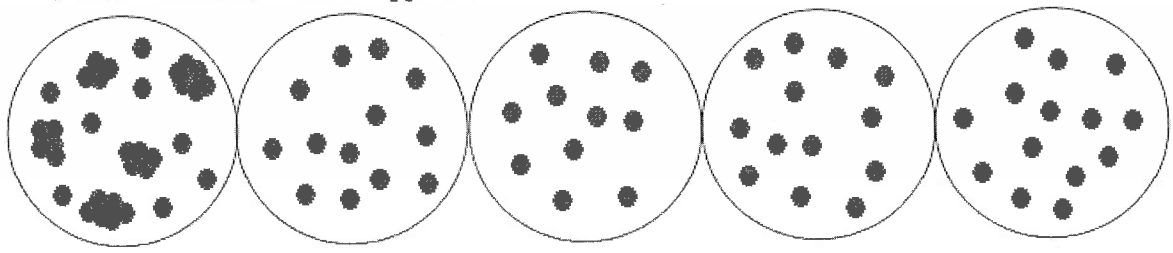
FMH RapidScreen Results Continued

Each Circle represents one 100x low-power field (10x objective lens with 10x ocular lens)

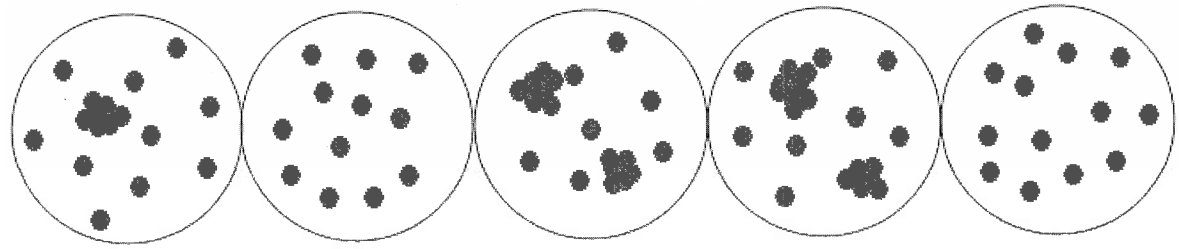
Positive Reaction – Total: 5 Agglutinates



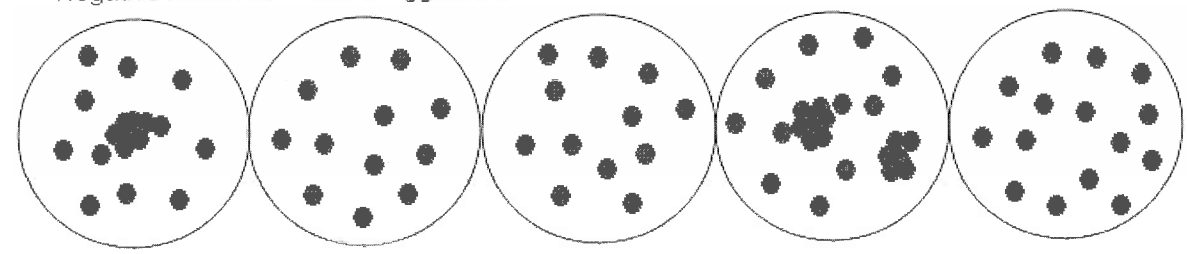
Positive Reaction – Total: 5 Agglutinates



Positive Reaction – Total: 5 Agglutinates



Negative Reaction – Total: 3 Agglutinates



REFERENCES

1. Immucor, Inc. Norcross, Georgia: Package insert,FMH RapidScreen
2. Standards for blood banks and transfusion services. 27th ed. Bethesda 2011; AABB
3. Judd WJ, Luban NLC, Ness PM, et al. Prenatal and perinatal immunohematology: recommendations of serologic management of the fetus, newborn infant, and obstetric patient. Transfusion 1990; 30:175-183
4. Kleihauer E. Braun H, Betke K. Demonstration von fetalem Hamoglobin in den Erythrozyten eines Blutausstriches. Klin Wschr 1957; 35:637

TechnicalCommunication

Additional Information for the FMH RapidScreen

This communication provides additional information for interpreting FMH RapidScreen results.

Fetal Bleed Screening Test (Old Test Method)	**Positive Test**[1]
	After examining nine low-power fields, if there are 3 or more clumps of agglutinated red blood cells are observed (i.e. on average, equal to or greater than one clump per three low-powered fields), the test is positive and indicates the presence of D-positive fetal red blood cells in possibly significant numbers in the maternal blood
	Negative Test[1]
	After examining nine low-power fields, if two or fewer clumps of agglutinated red blood cells are observed (i.e. on average, less than one clump per three low-power fields), the test is negative, indicating that a large feto-maternal hemorrhage did not occur.
	Specific Performance Characteristics[1]
	Fetal Bleed Screening Test, if carried out strictly in accordance with the recommended test procedure, will detect feto-maternal hemorrhage whenever 30 mL or more of ABO-compatible D-positive fetal blood has entered the maternal circulation. Depending on the care taken in carrying out the test, a positive result may be obtained when the extent of feto-maternal bleeding is less than 30 mL, but the test is designed to give a negative result when, as in most cases, the amount of fetal bleeding is small (e.g., less than 2 mL of whole blood).

[1] *Fetal Bleed Screening Test – Insert Code: 384-5, Revised 10/10*

FMH Rapid Screen (New Test Method)	**Positive Test**[2]
	After examining five low-power fields, if five or more agglutinates of red blood cells are observed, the test is positive and indicates the presence of D-positive fetal red blood cells in possibly significant numbers in the maternal blood.
	Negative Test[2]
	After examining five low-power fields, if four or fewer agglutinates of red blood cells are observed, the test is negative, indicating that a large feto-maternal hemorrhage did not occur.
	Specific Performance Characteristics[2]
	FMH RapidScreen, if carried out strictly in accordance with the recommended test procedure, will detect feto-maternal hemorrhage whenever 30 mL or more of ABO-compatible D-positive fetal blood has entered the maternal circulation. Depending on the care taken in carrying out the test, a positive result may be obtained when the extent of feto-maternal bleeding is less than 30 mL, but the test is designed to give a negative result when, as in most cases, the amount of fetal bleeding is small (e.g. less than 2 mL of whole blood.

[2] *FMH RapidScreen - Insert code: 3047-1, Revised 3/12*

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12/20/2012

Reviewed by/Date	Reviewed by/ Date	Reviewed by/date	Revised by/ Date
8-19-14			
5-27-15			
5-28-11			

Initial Implementation Date: _____

Taken out of Service: _____ Reason: _____

Reviewed by: _____ Date: 7/10/13
Department Supervisor

Reviewed by: Angela Lawster Date: 7/8/13
Department Adm. Director

Reviewed by: _____ Date: _____
Department Chief Technologist

Reviewed and Approved by: _____ Date: 7/8/13
Department Medical Director