FETAL CELL STAIN KIT
Screening Test for the Detection of Erythrocytes Containing Fetal Hemoglobin in Maternal Blood

"MODIFIED PROCEDURE FOR ROOM TEMPERATURE PROCESSING"

PRODUCT INFORMATION

KIT COMPONENTS

FETAL CELL FIXING SOLUTION (80% Reagant Alcohol)
FETAL CELL BUFFER SOLUTION (Citrate Buffer, 0.081M)
FETAL CELL STAIN (Erythrosin-B, Fast Green)

ORDERING INFORMATION

PROD. NO.		
S0412-00	FETAL CELL STAIN KIT	300 TEST
S0412-100	FETAL CELL STAIN KIT	100 TEST
S0411-06	CITRATE BUFFER SOLUTION	950 mL
S0412C	FIXING SOLUTION	950 mL
S0412A-100	STAINING SOLUTION	3X120 mL

The number of slides which may be prepared will vary with operator technique. NOTE: it is recommended that a control smear be prepared with each smear or group of smears to confirm acceptable stain performance.

REAGENT STABILITY

All reagents in the FETAL CELL STAIN KIT are stable when stored from 8-30°C for the period indicated on each kit and on each reagent bottle.

WARNING

1. All reagents in this kit should be handled with normal good laboratory techniques. Avoid contact with skin or eyes.
2. FETAL CELL FIX SOLUTION is flammable; avoid open flame.
3. For In-Vitro diagnostic use only.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Microscope capable of 250x magnification.
2. Timing device.
3. Glass microscope slides.
4. 0.85% saline solution.
5. Glass test tube.
6. Containers to fix, elute and stain slides.

SPECIMEN COLLECTION

Maternal blood sample should be collected in a syringe with a sterile needle or by evacuated technique, as soon after delivery as possible. (Cord blood is not acceptable for this procedure.) The blood is then treated with EDTA disodium salt (approximately 1.5 mg/mL) to prevent coagulation. Store sample at 2-4°C until it can be assayed. The blood should be assayed within 24 hours of collection.

PROCEDURE

1. Mix the blood sample well by gentle inversion.
2. Place 3 drops of 0.85% saline and 2 drops of maternal blood into a glass test tube. Mix by gentle agitation.
3. Place one drop of diluted blood on a glass slide near one end. Prepare thin film by drawing the edge of another slide through the drop of blood, and across the slide.
4. Air dry the slide at room temperature.
   NOTE: The slide should now be processed immediately throughout the entire procedure. It is recommended that the smear be viewed at 250x magnification to determine if a monolayer of cells has been obtained. If this has not been achieved, a new smear should be prepared.
5. Place the smears in a clean vessel containing sufficient FETAL CELL FIXING SOLUTION to cover the smears.
   Allow the smears to remain in the solution at room temperature for 5 minutes.
6. Remove the smears and rinse thoroughly in distilled water. Allow the slides to drain dry.
7. Place the smears in a clean vessel containing sufficient FETAL CELL BUFFER SOLUTION to cover the smears.
   Allow to remain in the solution at room temperature for 8-10 minutes.
8. Remove the slides from the solution and immediately place in a clean vessel containing FETAL CELL STAIN.
   Stain for 3 minutes.
9. Remove the slides from the FETAL CELL STAINING SOLUTION and rinse thoroughly in distilled water. Dry the slides at room temperature.
10. Slides may be examined either dry or using oil-immersion. Fetal cells will stain a dark reddish-pink while adult cells will appear white to light pink with a darker center. Staining intensity of adult cells may vary slightly within lots of reagents, however, fetal and adult cells will be easily differentiated. The slides should be read within 24 hours.

CONTROL

A positive control may be prepared from a mixture of 1 part cord blood and 9 parts normal adult blood. This control preparation is then assayed in the same manner as the patient sample. This yields a qualitative confirmation of the stain performance.

SIMMLER

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REV. 3/06

RESULTS

The common means of reporting fetal cells is as a ratio of normal adult cells. This ratio is achieved by randomly observing 8-10 fields of cells at 250x magnification. Count the number of adult cells in each field and total them. Count the number of fetal cells in each of the same fields and total the fetal cells. Determine the ratio of fetal cells to adult cells by dividing the total number of fetal cells counted by the number of adult cells counted.

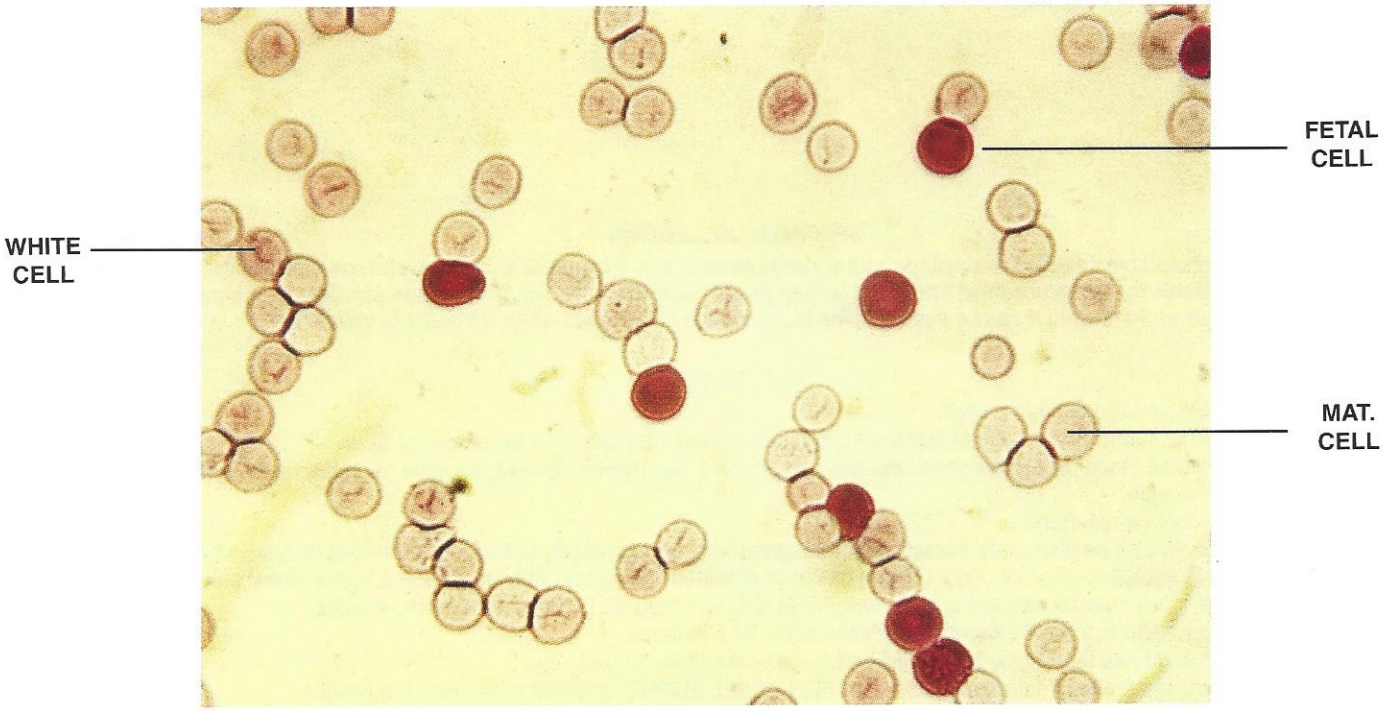
EXAMPLE:		
	Total # Fetal RBC's Counted	26
	Total # Adult RBC's Counted	4435
	Fetal RBC's/Adult RBC's Ratio	0.0058

RhoGAM DOSAGE

The number of vials of RhoGAM necessary to protect against Rh immunization is based on the fetal/adult RBC ratio calculated.

FETAL/ADULT RBC RATIO	VOLUME OF FMH	VIALS OF RhoGAM INDICATED
0.0 to 0.0045	up to 15 ml	1
0.0046 to 0.0090	from 15 to 30 ml	2
0.0091 to 0.0135	from 30 to 45 ml	3
0.0136 to 0.0180	from 45 to 60 ml	4
0.0181 to 0.0225	from 60 to 75 ml	5

For each ratio interval of .0045, one additional vial of RhoGAM is indicated. If the dose calculation results in a fraction, administer the next number of whole vials of RhoGAM.



SOURCES OF ERROR

1. Hematological disorders in adults may produce increased levels of fetal-type cells. (3,5)
2. The degree of elution of the adult hemoglobin may vary from patient to patient.
3. Normal adult blood contains less than 1.0% of fetal-type hemoglobin. (5)
4. Lymphocytes may take up stain in varying degrees, but less than fetal cells. (See picture above)

REFERENCES

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