



Touching lives that haven't yet begun.

FETALSCREEN™ II
Fetal Maternal Hemorrhage Screening Test



Announcing a new addition to the Ortho Clinical Diagnostics family of products for the early detection, prevention, and management of Hemolytic Disease of the Newborn (HDN). The FETALSCREEN™ II Screening Test for Detection of D (Rho) positive fetal red blood cells in maternal circulation further expands upon the commitment of Ortho Clinical Diagnostics to help protect mothers and their babies.

The FETALSCREEN™ II Fetal Maternal Hemorrhage Screening Test provides

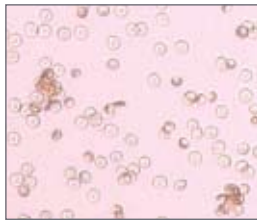
- + Accuracy
- + Consistency
- + Simplicity

Key Benefits

+ Simple, easy interpretation of results

Enzyme-treated indicator cells provides robust reactivity and clarity of results

Fewer microscopic fields simplifies reading and interpretation of results¹



+ Cost effective screening method for routine use

New package size of 100 tests increases testing capacity

Eliminates time/technique intensive quantitative test methods

+ Meets the expected standard of detection for Rh positive fetal cells

Confidence in providing appropriate treatment at a defined standard^{2,3}.

+ Can be performed in the blood bank

One stop ordering for all of your blood bank testing needs

+ Confidence in outcomes

Accurate results saves time and money

Ensure stability with innovative blend of monoclonal antibodies

¹Based on IFU comparison

²E.S. Sebring & H.F. Polesky. Fetomaternal Hemorrhage: incidence, risk factors, time of occurrence, and clinical effects; TRANSFUSION 1990; 30:344-357

³Haywood L. Brown. Trauma in Pregnancy. American College of Obstetricians and Gynecologists; 2009; 114:147-160

FETALSCREEN™ II FMH Test together with RhoGAM® Brand provides a platform to aid in the screening and prevention of HDN. Rh-negative women with a fetomaternal hemorrhage (FMH) of Rh-positive blood are at increased risk of Rh immunization and the outcome of their current and future pregnancies may be affected.

For more detailed information regarding the safe and effective use of RhoGAM® Brand please see the full prescribing information on www.rhogam.com.

IMPORTANT SAFETY INFORMATION

RhoGAM® and MICRhoGAM® Ultra-Filtered PLUS Rho(D) Immune Globulin (Human) are made from human plasma. Since all plasma-derived products are made from human blood, they may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent. RhoGAM® and MICRhoGAM® are intended for maternal administration. Do not inject the newborn infant. Local adverse reactions may include redness, swelling, and mild pain at the site of injection and a small number of patients have noted a slight elevation in temperature. Patients should be observed for at least 20 minutes after administration. Hypersensitivity reactions include hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. RhoGAM® and MICRhoGAM® contain a small quantity of IgA and physicians must weigh the benefit against the potential risks of hypersensitivity reactions. Patients who receive RhoGAM® and MICRhoGAM® for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction.

