

## THE ORTHO CLINICAL DIAGNOSTICS FRANCHISE



### Hemolytic Disease of the Newborn

Hemolytic Disease of the Newborn (HDN) can develop when the Rh-negative blood of a pregnant woman comes in contact with the Rh-positive blood of her fetus. Rh-negative blood does not have a certain protein (the Rh antigen), and is not compatible with Rh-positive blood. Therefore, the woman's body produces antibodies that attack the blood of the fetus<sup>1</sup>. This reaction usually does not affect the first pregnancy, but once the mother has been sensitized and produces Rh antibodies, all future pregnancies are at risk. HDN may lead to serious complications in the baby, such as severe anemia, brain damage and, in some cases, even death.

Prior to the introduction of Rh immune globulin products, like RhoGAM<sup>®</sup> Brand more than 40 years ago, nearly 10,000 babies died from HDN each year in the United States<sup>2</sup>. Today, HDN has been substantially reduced due to the safe and effective use of Rh immune globulin products.

#### RhoGAM<sup>®</sup> Rho(D) Immune Globulin (Human)

RhoGAM<sup>®</sup> Brand, the worldwide market leader<sup>3</sup>, is the first Rh immune globulin product developed to help protect Rh-negative women in the prevention of HDN. RhoGAM<sup>®</sup> Brand has maintained a 40-year record of proven safety, efficacy and uninterrupted product supply. Plasma for RhoGAM<sup>®</sup> Brand is solely sourced from a dedicated collection site of unique donors. One-third of the donors have been contributing to the program for more than 10 years. RhoGAM<sup>®</sup> Brand prevents Rh-negative women's bodies from making antibodies that would destroy Rh-positive cells in future pregnancies. Prior to RhoGAM<sup>®</sup> Brand, physicians resorted to administering blood transfusions to babies still in the womb, or conducting complete exchange transfusions shortly after birth.



#### FETALSCREEN<sup>®</sup> II Fetal Maternal Hemorrhage Screening Test

The FETALSCREEN<sup>®</sup> II Screening Test was launched in 2009 for the detection of HDN. It is a simple and qualitative test that detects D (Rho) positive fetal red blood cells in the maternal circulation of pregnant Rh-negative women. This test uses innovative technology to provide accurate and consistent results. Among the improvements over previously available tests are: the use of an innovative blend of monoclonal antibodies for stability and accuracy; enzyme-treated indicator cells to facilitate robust reactivity and results clarity; and fewer microscopic fields to simplify results reading and interpretation. The FETALSCREEN<sup>®</sup> II Screening Test can be performed in both hospitals and blood banks.

### **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.

For more detailed information regarding the safe and effective use of RhoGAM® Brand please see the full prescribing information on [www.RhoGAM.com](http://www.RhoGAM.com).

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<sup>1</sup> The Rh Factor. American College of Obstetricians and Gynecologists. 2005. Check reference

<sup>2</sup> Zimmerman D.R. Rh: *The Intimate History of a Disease and its Conquest*. New York, N.Y.: MacMillan Publishing Company, May 1973.

<sup>3</sup> Based on market share; OCD Data on File