


PERINATAL

Control cells to validate the procedures for detection of **Fetomaternal Hemorrhage**

FETALtrol™

Special features

- Eliminates the need to acquire cord blood to make *home brew* controls, saving time precious to the laboratory workforce
- Three validated levels which correspond to clinical decision points for anti-D therapy
- FDA cleared as a hematologic control for fetal red cell detection
- 3 months total shelf life
-  IVD CE

Applications

- Flow cytometric methods
- Kleihauer-Betke tests
- EQA programs

Background information

Detection and quantification of fetal red blood cells (fRBCs) in maternal blood samples is essential for obstetrical management. Measurement of fRBCs is critical as the extent of Fetomaternal Hemorrhage (FMH), the transplacental passage of fRBCs into the maternal circulation, has consequences for further treatment of mother and child. Frequency and size of FMH is directly influenced by complications in abdominal trauma, suspected placental injury or a cesarean section. Severe FMH may lead to intra-uterine death. In case of antigen incompatibility between mother and child FMH may result in respiratory problems or anemia, like Hemolytic Disease of the Newborn.

Principle of the FETALtrol™

The laboratory determination of the level of fRBCs in maternal circulation remains an important support in the obstetrical management of women with suspected uterine trauma and in the proper dose administration of Rh immune globulin. Limitations in the sensitivity and precision of the widely used manual Kleihauer-Betke method have prompted an increased utilization of flow cytometric methods for fetal RBC detection in maternal blood samples. The anti-HbF flow cytometric method for detection of fRBCs offers a simple, reliable and more precise alternative to the Kleihauer-Betke manual technique for the assessment of fetomaternal hemorrhage. The method has additional potential applications for the study of HbF levels or frequency of adult RBCs with low levels of HbF (F cells) in individuals with hemoglobinopathies. FETALtrol™ is a 3-level control set that can be used to validate and monitor the quality of both flow cytometric and Kleihauer-Betke manual procedures for the detection of FMH.

Item	Description	Regulatory status	Package size	Product code
FETALtrol™ ¹	Tri-level stabilized blood controls with known human fetal erythrocytes content in human adult blood	IVD CE and FDA cleared	3 levels, two 2 mL vials each level	FH101
			3 levels, one 2 mL vial each level	FH102

Related products				
Item	Description	Regulatory status	Package size	Product code
Fetal Cell Count™ kit	Complete assay for routine diagnosis of Fetomaternal Hemorrhage using anti-HbF and anti-CA	IVD CE	25 tests	IQP-363
FMH QuikQuant™	Rapid assay for Fetomaternal Hemorrhage Quantification	IVD CE	100 tests	QQF-100
FMH kit ²	FITC conjugated anti-RhD reagent for determination of Fetomaternal Hemorrhage	IVD CE	100 tests	9447

IVD CE in vitro diagnostic medical device. The products are registered as IVD in the countries belonging to the European Union

¹ Distributed for R&D Systems, USA

² Distributed outside the UK for IBGRL Bristol, UK