


Diagnosis of Fetomaternal Hemorrhage based on Flow Cytometry



Fetal Cell Count™ Kit

Special features

- Unique quantification of Fetomaternal Hemorrhage by flow cytometry ^(1,2)
- Results in 90 minutes
- Complete assay for routine diagnosis of Fetomaternal Hemorrhage ^(1,2)
- Detection as low as 0.02% fetal cells in maternal blood
- Detection of fetal hemoglobin (HbF) and Carbonic Anhydrase (CA)
- For use with flow cytometer
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Applications

- Determination of Fetomaternal Hemorrhage ^(1,2)
- Pregnancy with suspected RhD incompatibilities ⁽¹⁾
- Abdominal trauma ⁽²⁾
- Recognizes fetal cells in maternal Thalassemia circulation ⁽³⁾

References

1. Valérie Porra et al., Identification and quantification of fetal red blood cells in maternal blood by a dual-color flow cytometric method: evaluation of the Fetal Cell Count™ Kit, *Transfusion*, 2007;47:1281-1289.
2. Liesbeth Bakker-Jonges et al., The Detection of Foetal Red Blood Cells in Maternal Blood Samples by dual Flow Cytometry, *Haematology*, 2008;58-60.
3. Leers et al., Discriminating fetomaternal hemorrhage from maternal HbF-containing erythrocytes by dual-parameter flow cytometry, *European Journal of Obstetrics and Gynecology and Reproductive Biology*, 2006.

This method is protected by EU patent 1,423,706 and US patent 7,485,433

Background information

Fetomaternal Hemorrhage (FMH), the transplacental passage of fetal red blood cells (fRBCs) into the maternal circulation, can be caused by complications in abdominal trauma, suspected placental injury or a cesarean section. Severe FMH may lead to intra-uterine death. In case of antigen (RhD) incompatibility between mother and child, FMH may result in Hemolytic Disease of the Newborn. In this case, correct enumeration of the amount of fRBCs is essential for (prophylactic) anti-D therapy.

Several methods exist to quantify the extent of FMH by enumeration of fRBCs, including the Kleihauer-Betke acid-elution test and single-color anti-HbF flow cytometry test. For both methods, correct interpretation of results might be compromised due to the presence of adult RBC's that express HbF, called F cells. These F cells may be present in patients suffering from thalassemia, sickle cell anaemia or hereditary persistence of fetal haemoglobin.

Principle of the Fetal Cell Count™ Kit

The Fetal Cell Count™ kit is based on a patented combination of two antibodies. One is directed against HbF while the second is specific for carbonic anhydrase, an enzyme present in adult RBCs, and at very low detectable level, in late pregnancy stage. This unique combination allows clear discrimination between fRBCs, (carbonic anhydrase containing) adult RBCs, and F cells.

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
Related Products				
Item	Description	Regulatory status	Package size	Product code
FMH QuikQuant™	Rapid assay for Fetomaternal Hemorrhage Quantification	IVD CE	100 tests	QQF-100
FMH Kit ¹	FITC conjugated Anti-RhD reagent for determination of Fetomaternal Hemorrhage	IVD CE	100 tests	9447
FETALtrol™ ²	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

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

¹ Distributed outside the UK for IBGRL, Bristol, UK

² Distributed for R&D Systems, USA