PERINATAL

Rapid assay for Fetomaternal Hemorrhage based on Flow Cytometry

FMH QuikQuant™

Special features

- Detection of fetal hemoglobin (HbF) of as low as 0,06% fetal cells in maternal blood
- Results in 1 hour (20 minutes hands-on-time) with two single centrifuge steps
- For use with flow cytometer
- IVD CE

Applications

- Determination of Fetomaternal Hemorrhage
- Pregnancy with suspected RhD incompatibilities

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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. A small percentage of adult RBC's may express fetal hemoglobin (HbF), these RBCs are termed F-cells. F-cells could generate false positive results in the Kleihauer-Betke acid-elution test or a single-color anti-HbF flow cytometry test. Presence of F-cells may be the result of physiological variations during pregnancy or traits such as thalassemia, sickle cell anemia or hereditary persistence of fetal hemoglobin. The detection (and thus enumeration) of fRBCs is used to calculate the extent of FMH, either in case of trauma with suspected placental injury or in the situation of a RhD incompatibility between the fetus and the mother. The level of FMH is a measure to determine the (prophylactic) anti-D therapy for prevention of hemolytic disease of the newborn.

Principle of the FMH QuikQuant™

The FMH QuikQuant™ uses an anti-Hemoglobin F monoclonal antibody and Propidium Iodide reagent. With less than 20 minutes of hands-on time, the FMH QuikQuant™ is a two-step wash technique requiring about 1 hour to complete.

Item	Description	Regulatory status	Package size	Product code
FMH QuikQuant™	Rapid assay for Fetomaternal Hemorrhage Quantification	IVD CE	100 tests	QQF-100

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 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

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