NEW!

IQ Products®
bright fluorescence

Rozenburglaan 13a
9727 DL Groningen
The Netherlands
Tel. +31 (0)50 57 57 000
Fax +31 (0)50 57 57 002
Email marketing@iqproducts.nl
Web **www.iqproducts.nl**

Diagnosis of Feto-maternal hemorrhage

Fetal Cell Count™ Kit

Improved product

- Less procedural steps
- More than 20 minutes reduction in hands-on-time
- Direct labeled antibodies

Application areas

- Cases with possible RhD incompatibilities
- Abdominal trauma
- Preeclampsia
- Blood loss during pregnancy
- Intra-Uterine Transfusion (IUT)

patented methodology

Special features

- Quantitation of Feto-maternal hemorrhage by flow cytometry
- Detection of as low as 0.02% fetal cells in maternal blood
- Intracellular detection of fetal hemoglobin (HbF) and carbonic anhydrase (CA)
- IVD CE

NEW!

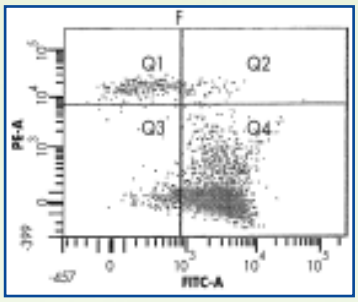
Fetal Cell Count™ Kit

Routine diagnosis of Fetomaternal hemorrhage using the Fetal Cell Count™ kit

Detection and quantification of fetal red blood cells (RBCs) in maternal blood samples is essential for obstetrical management. Measurement of fetal RBCs is critical as the extent of Fetomaternal hemorrhage (FMH), the transplacental passage of fetal RBCs 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 after a caesarean 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.

The Kleihauer-Betke acid-elution test allows for FMH measurements. However, it tends to be inaccurate and overestimates the FMH since populations of HbF containing adult RBCs (F-cells) in the maternal blood flow can be present that also will be positive in the test. These 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.

Less tedious and more accurate is the use of flow cytometry to measure fetal cells using antibodies to HbF. Discrimination between maternal and fetal RBCs is based on the slightly lower expression of HbF in the maternal population. An adequate setting to differentiate these HbF containing cells, however is difficult to achieve and subjective.
To circumvent the need for an arbitrary setting, the Fetal Cell Count™ kit (IQP-379) is designed to identify the number of fetal cells in maternal blood in a rapid and reliable way. The Fetal Cell Count™ kit assay is based on a patented combination of two antibodies. One is directed against HbF while the second is specific for carbonic anhydrase (CA), an enzyme present in adult RBCs and, at very low detectable level, in late pregnancy stage.
Using the Fetal Cell Count™ kit, the amount of fetal RBCs in the maternal blood circulation can be determined within 70 minutes. Precise and accurate detection of even as low as 0.02% fetal RBCs make this kit a powerful tool for the diagnosis of FMH.



A typical Fetal Cell Count™ Kit result emphasizing its clinical utility in the diagnosis of fetomaternal hemorrhage and the subsequent treatment.

Q1: fetal RBCs (HbF^{++}/CA^{-}) - Q2: HbF^{+}/CA^{+} cells (F-cells and to an allowed degree fetal cells at late gestational stage) - Q3: non-stained cells (HbF^{-}/CA^{-}) / Q4: adult RBCs and F-cells (HbF^{-}/CA^{++}).
Since the percentage of contaminating F-cells and their expression level of HbF is variable, the overestimation introduced by identification through HbF content alone can be proportionally high. The percentage of F-cells to be expected in a patient sample ranges in between 0 -14%. The data emphasize the significance of CA and HbF as markers for accurate discrimination of the different RBC populations in maternal blood. Without the use of CA as marker, discrimination between the fetal RBCs and the variable concentrations of HbF containing maternal F-cells becomes less precise.

PRODUCT DETAILS

Item	Description	Test size	Product code
Fetal Cell Count™ IVD	Complete assay for the diagnosis of Fetomaternal hemorrhage by flow cytometry	25 tests	IQP-379

RELATED PRODUCTS

Item	Description	Test size	Product code
Fetaltrol™ IVD FDA	FDA cleared process control in the diagnosis of Fetomaternal hemorrhage by flow cytometry and/or Kleihauer-Betke staining	3x2 mL each	IQP-370FT

SINGLE COLOR REAGENTS AGAINST HUMAN ERYTHROCYTE ANTIGENS

Item	Clone	Isotype	Cellular expression	
Anti-D	NaTH109-1G2	Hu IgG	Rh D antigen (RH1)	IQP-513R

References
1. Porra V, Bernaud J, Gueret P, Bricca P, Rigal D, Follea G, Blanchard D. 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 Jul;47(7):1281-9.
2. Leers MP, Pelikan HM, Salemans TH, Giordano PC, Scharnhorst V. Discriminating fetomaternal hemorrhage from maternal HbF-containing erythrocytes by dual-parameter flow cytometry. Eur J Obstet Gynecol Reprod Biol. 2006.

CE

IQ Products BV has a Quality System in place based on ISO13485:2003 and in compliance with USFDA QSR (21CFR820).
Yearly inspection by TNO Certification Medical, Leiden.