

Easy-K

Kleihauer-Betke test

Test for Identification of Fetomaternal Hemorrhage




Key Benefits

- Detection and quantification of hemoglobin-F containing red blood cells in blood smears
- Ready-to-use reagents
- Microscopic analysis

Applications

- Identification of fetomaternal hemorrhage in:
 - Pregnancy with suspected RhD incompatibilities
 - Abdominal trauma

Features

- Method based on acid elution of hemoglobin-A
- Stains 30 microscopic slides
- Including positive and negative control slides
- Hemalum included to exclude small lymphocytes
-  CE

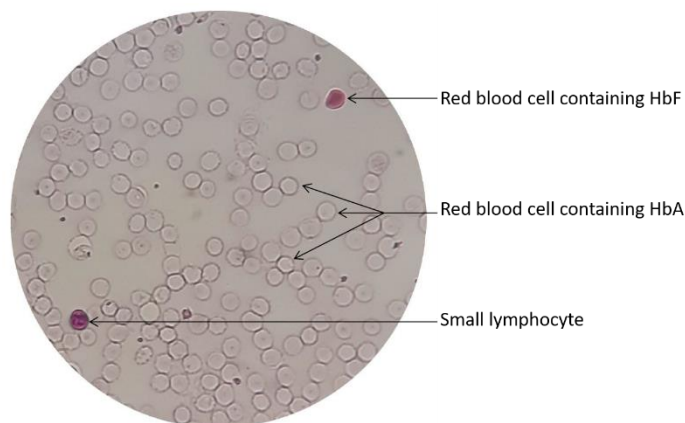
Background information

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 situation, correct enumeration of the amount of fRBCs is essential for (prophylactic) anti-RhD therapy.

Several methods exist to quantify the extent of FMH by enumeration of fRBCs, including the Kleihauer-Betke acid-elution test and flow cytometry tests.

Principle of the Easy-K Kleihauer-Betke test

The Easy-K distinguishes red blood cells which express hemoglobin-F (HbF) from those containing hemoglobin-A (HbA). Red blood cells containing HbF are resistant to acid treatment, while cells containing HbA are sensitive for acid treatment. The HbF remaining in the red blood cells is then stained with a pink dye, so the HbF containing red blood cells can be distinguished from the uncoloured red blood cells that used to contain HbA. Microscopic analysis is used to count the number of HbF containing red blood cells per HbA containing red blood cells, which will be expressed in percentage. From this percentage the millilitre transfusion can be calculated.



| Item | Description | Regulatory status | Package size | Product code |
|-------------------------|---|------------------------|------------------------------------|--------------|
| Easy-K ¹ | The Easy-K is intended for performing the Kleihauer-Betke test for the detection and quantification of fetomaternal hemorrhage. | IVD CE | 30 tests | 901080234 |
| 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 |
| FETALtrol™ ² | Tri-level stabilized blood controls with known human fetal erythrocytes content in human adult blood. | IVD CE and FDA cleared | 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 for Institute de Biotechnologies Jacques Boy, France

² Distributed for R&D Systems, USA