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

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 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 anaemia, like Haemolytic Disease of the Newborn.

Principle of the FETALtrol™

The laboratory determination of the level of fetal cells 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 cell detection in maternal blood samples. The anti-HbF flow cytometric method for detection of fetal cells offers a simple, reliable and more precise alternative to the KB manual technique for the assessment of fetomaternal hemorrhage. The method has additional potential applications for the study of HbF levels or frequency of adult red cells 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.

![Product Flyer](image)

**Item** | **Description** | **Package size** | **Product code**
---|---|---|---
FETALtrol™<sup>™</sup> <sub>IVD</sub> | Tri-level stabilized blood controls with known human fetal erythrocytes content in human adult blood | 3 levels, two 2 mL vials each level | FH101
FETALtrol™<sup>™</sup> <sub>IVD</sub> | Tri-level stabilized blood controls with known human fetal erythrocytes content in human adult blood | 3 levels, one 2 mL vial each level | FH102

**Related products**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Package size</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetal Cell Count™ kit &lt;sub&gt;IVD&lt;/sub&gt;</td>
<td>Complete assay for routine diagnosis of Fetomaternal Hemorrhage using anti-HbF and anti-CA</td>
<td>25 tests</td>
<td>IQP-363</td>
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<tr>
<td>FMH QuikQuant &lt;sub&gt;IVD&lt;/sub&gt;</td>
<td>Rapid assay for Fetomaternal Hemorrhage Quantification</td>
<td>100 tests</td>
<td>QQF-100</td>
</tr>
<tr>
<td>FMH kit&lt;sup&gt;2&lt;/sup&gt; &lt;sub&gt;IVD&lt;/sub&gt;</td>
<td>FITC conjugated anti-RhD reagent for determination of Fetomaternal Hemorrhage</td>
<td>100 tests</td>
<td>9447</td>
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<sup>™</sup> in vitro diagnostic medical device. The products are registered as IVD in the countries belonging to the European Union.

<sup>1</sup> Distributed for R&D Systems, USA

<sup>2</sup> Distributed outside the UK for IBGRL Bristol, UK