Haemoglobin FASC Variant Control

Description and Intended Use

The extendSURE™ Haemoglobin FASC Control [CONTROL] is a stabilised lyophilised control containing human haemoglobin F, A, S and C. The lyophilised controls are prepared from human adult haemolysate and foetal cord lysate.

In order to assist in the correct identification of variant haemoglobin when analysing a patient blood sample it is important to have a control that contains appropriate known abnormal haemoglobins to monitor the performance of the analytical system. The Haemoglobin FASC control is intended to be used as a position marker monitor for haemoglobin variant analysis methods and to assess assay reproducibility in the following assay types: ion exchange HPLC, capillary electrophoresis, cellulose acetate and agar/agarose gel electrophoresis and iso-electric focusing. The control will enable clear definition of the elution time on HPLC or capillary electrophoresis or migration distance on electrophoresis or iso-electric focusing. For specific application in a particular assay refer to the analyser's operating manual. The control is not to be used as a calibrator.

Good laboratory practice dictates that a quality control program be established in all laboratories. This program consists of the routine assay of this control by trained laboratory personnel and evaluation of the documented results against laboratory acceptable limits. If results are outside these limits re run the control and investigate method parameters, environmental factors and techniques. If after re-running the control the result(s) continues to remain outside the acceptable limits, contact the manufacturer of the control for further control interpretation assistance.

Further good laboratory practice dictates that control samples and results be quarantined from patient samples and results.

Kit Contents

REF HB610

Description:
- 4 bottles of extendSURE™ Haemoglobin FASC Control (1.0mL when reconstituted). Each control contains a preparation of lyophilised human whole blood and cryoprotectants, a broad spectrum antibiotic and stabilisers.
- 2 bottles of extendSURE™ Haemoglobin FASC Reconstitution Fluid (2.5 mL).
- 1 Information Sheet.

Precautions/Warnings

WARNING

 риск Потentially Biohazardous Material

Human red cells were used as a source material in the manufacture of the control. Each unit was obtained from blood donors and tested by FDA accepted methods and found non reactive for Hepatitis B surface antigen, Anti-HCV, Anti-HIV 1 & 2 and Syphilis. No test method can offer complete assurance that the control containing human sourced materials will be absent of these and other infectious agents. Good laboratory practice dictates that all human source material should be considered potentially infectious and be handled with the same precautions used with patient specimens.
CAUTION

- Please READ through this INFORMATION SHEET before using the control material.
- FOR IN VITRO DIAGNOSTIC [IVD] USE.
- SAFETY CLOTHING (glasses, gloves and laboratory coat) are RECOMMENDED when using these controls.
- Discarded or spilt controls should be treated and disposed of as directed by your laboratory safety guidelines or by local ordinance.
- This PRODUCT CONTAINS a small amount of POTASSIUM CYANIDE. DO NOT INGEST.
- The RECONSTITUTION FLUID CONTAINS 0.09% SODIUM AZIDE which may react with Copper or Lead plumbing to form explosive metal azides. Use caution in disposing of control solutions. If disposing to drain, flush with large volumes of water to prevent azide build up.
- DO NOT USE CONTROLS BEYOND EXPIRY DATE and only use one control lot at a time.

Storage and Handling

Dry Product (Prior to Reconstitution)

The extendSURE™ Haemoglobin FASC Control should be stored at 2-8°C. The closed vial of control can be used until the last day of the expiration month shown on the bottle and is stable for 36 months from the date of manufacture.

THE APPEARANCE OF MOISTURE OR BROWN COLOURED FREEZE DRIED CAKE IN THE BOTTLE, PRIOR TO RECONSTITUTION, IS AN INDICATION OF DETERIORATION OF THE MATERIAL AND RENDERS THE MATERIAL UNSATISFACTORY FOR USE.

Reconstituted

The extendSURE™ Haemoglobin FASC Control should not be frozen. Do not allow it to stand uncapped. The Control may remain at room temperature for 30 minutes during testing, but should be returned to a refrigerator in an upright position and tightly capped at all times. Discard any reconstituted control solution that appears cloudy, shows evidence of precipitation or is obviously contaminated. The reconstituted control is stable for 6 weeks when stored at 2-8°C.

Reconstitution

The following instructions for reconstitution are recommended to ensure a homogeneous control solution and minimise variation resulting from different reconstitution methods in different laboratories.

1. Remove the control and reconstitution fluid bottles from the refrigerator just prior to reconstitution.
2. Gently tap the bottom of the control bottle on the lab bench in order to collect as much material as possible on the bottom of the bottle.
3. Carefully remove the caps from both bottles.
4. Using a pipette add 1.0 mL of the Reconstitution Fluid (0.09% sodium azide solution) to the control bottle and replace both caps.
5. The control should be allowed to stand at room temperature for 15 minutes.
6. After 15 minutes coat all surfaces of the control bottle by rotating and inverting the bottle. Continue gentle mixing by swirling the bottle until the solution is homogeneous and all lyophilised material is reconstituted. This gives a stable haemolysate solution of approximately 4.0 to 5.0 g/dL total haemoglobin.

7. If the lyophilised material does not fully dissolve within 15 minutes discard the material and reconstitute a new bottle.

**LOT XXXX**

**Result Interpretation**

For evaluation of band positions or retention times and levels of haemoglobin variants refer to the procedures recommended by instrument/method manufacturer.

As an example the retention times and levels of haemoglobin variants below have been determined using the BioRad Variant Beta Thalassaemia Short Program. These values are NOT certified values and because other assay systems may produce different values it is necessary to establish a mean value and range about the mean for each assay system.

<table>
<thead>
<tr>
<th>HbF</th>
<th>HbA</th>
<th>HbS</th>
<th>HbC</th>
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<tbody>
<tr>
<td>Retention Time (Mins)</td>
<td>%</td>
<td>Retention Time (Mins)</td>
<td>%</td>
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</table>

**In vitro Diagnostic Directive (IVDD, 98/79/EC) Symbols**

**In Vitro Diagnostic Medical Device**

**Authorised Representative in the European Community**

Manufacturer: MDCPartners

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