CE Marked Material
Human anti-Haemophilus influenzae b reference serum
NIBSC code: 09/222
Instructions for use
(Version 7.0, Dated 05/03/2018)

This material is a self certified IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC".

1. INTENDED USE
This product is CE marked for use as an IVD within the EU member states and EEA countries. In all other territories this product can be used for research purposes only.

Sera from single donors, collected in the United Kingdom. Each ampoule contains 0.5 ml of crude pooled sera, freeze-dried and lyophilized. The material is stored in a glass ampoule, with a pyrogen-free stopper and a DIN neck. Individual ampoules are packed in a polystyrene container with the following components:

- Ampoules (x 1)
- Product information sheet (x 1)
- Certificate of analysis (x 1)
- Safety data sheet (x 1)
- Brochure (x 1)

2. CAUTION
This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBSAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory’s safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE
Each ampoule contains 41.3 µg of total immunoglobulins to Hib polysaccharide (PRP). Of this, 34.7 µg is IgG and 2.8 µg is IgM antibodies, as determined by in house calibration against the WHO Lot 1983 reference serum, at the National Institute for Biological Standards & Control (NIBSC) using in house ELISA

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried residue of 0.5ml of neat pooled human serum.

5. STORAGE
Unopened ampoules should be stored at -20°C.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING
DIIN ampoules have an ‘easy-open’ coloured stress point, where the narrow ampoule stem joins the wider ampoule body.
Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.

Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A disposable ampoule breaker is provided with each DIN ampoule.

7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

The entire contents of each vial should be completely re-suspended in 0.5ml of phosphate-buffered saline. Single use aliquots stored at -20°C of the reconstituted material is stable for up to 6 months.

If package is damaged do not use the material.

Customers to assess fitness of reference serum for purpose.

Product has a shelflife of 30 years, do not use after the expiry date shown on the label.

8. STABILITY
Accelerated degradation study carried out at NIBSC showed the material is very stable with a predicted loss of activity per year of 0.054% for anti-Hib IgG antibodies. In addition a real time stability study is ongoing to monitor the performance of the standard.

Users who have data supporting any deterioration in the characteristics of Reference Materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference serum should be stored on receipt at -20°C.

9. REFERENCES

10. ACKNOWLEDGEMENTS
We are very grateful for Prof. Andrew Pollard, Dr. Maheshi Ramasamy and Dr Chaam Klinger from the Oxford Vaccine group, Oxford, UK for providing the anonymous donation of the immune sera. Grateful acknowledgements are due to the Center for Biologics Evaluation and Research, FDA, US, MD, USA for provision of ampoules of FDA lot 1983 Hib reference serum for calibration of our reference preparation.

11. FURTHER INFORMATION
Further information can be obtained as follows:
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK
Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

Madore DV, Johnson CL, Phipps DC, Myers MG, Eby R, Smith DH. Safety

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13. CITATION
In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance:</td>
<td>Freeze dried powder</td>
</tr>
<tr>
<td>Corrosive:</td>
<td>No</td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
</tr>
<tr>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>Yes</td>
</tr>
<tr>
<td>Irritant:</td>
<td>No</td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
</tr>
<tr>
<td>Handling:</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Contains material of human origin</td>
</tr>
</tbody>
</table>

Toxicological properties

Effects of inhalation: Not established, avoid inhalation
Effects of ingestion: Not established, avoid ingestion
Effects of skin absorption: Not established, avoid contact with skin

Suggested First Aid

Inhalation: Seek medical advice
Ingestion: Seek medical advice
Contact with eyes: Wash with copious amounts of water. Seek medical advice
Contact with skin: Wash thoroughly with water.

Action on Spillage and Method of Disposal

Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

15. LIABILITY AND LOSS
In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents. Unless expressly stated otherwise by NIBSC, NIBSC’s Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient’s attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom
* Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.

Net weight: 0.0463g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable, Attached: No