Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Human anti-Haemophilus influenzae b reference serum
NIBSC code: 09/222
Instructions for use
(Version 9.0, Dated 16/06/2023)

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 UK, EU member states and EEA countries. In all other territories this product can be used for research purposes only.
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Serological analysis by Enzyme-linked immunosorbent assays (ELISAs) has been widely used for evaluation of antibody responses to Heamophilus influenzae b (Hib) vaccination and infection. The freeze-dried anti-serum (ampoule code 09/222) was prepared from pooled human sera kindly donated by Prof. Andrew Pollard, Oxford University, United Kingdom. This material contains antibodies specific for the capsular polysaccharide (polyribosyl ribitol phosphate; PRP) of Hib which is one of the main virulence factors and is the active component of Hib vaccines.
This reagent is to be used as a reference standard for quantification of anti-PRP IgG antibodies by ELISA. The reagent could also be used to measure total Ig and IgM levels for additional information.

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, 34.7µg is IgG and 2.8 µg is IgM antibodies, as determined by in house calibration against the FDA 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

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

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 -20oC of the reconstituted material is stable for up to 6 months.
If package is damaged do not use the material.
Customers to asses 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 -20oC.

9. REFERENCES

Madore DV, Johnson CL, Phipps DC, Myers MG, Eby R, Smith DH. Safety and immunogenicity of Haemophilus influenzae type b oligosaccharide-CRM197 conjugate vaccine in infants aged 15 to 23 months. Pediatrics. 1990 Oct;86(4):527-34.

10. ACKNOWLEDGEMENTS

EC REP: Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

We are very grateful for Prof. Andrew Pollard, Dr Maheshi Ramasamy and Dr Chaam KLinger ffrom the Oxford Vaccine group, Oxford, UK for organising the 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 prepartion.

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:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE

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

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

Physical and Chemical properties			
Physical appearance: Freeze dried powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains material of human origin This serum was tested for bacterial and fungal growth and found to be sterile.		

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