Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Anti-Meningococcal Serogroup A/C Reference Serum Pool, CDC 1992
NIBSC code: 99/706
Instructions for use
(Version 7.0, Dated 11/07/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is for use as a control in ELISA assays to assess the levels of antibody in human serum following vaccination with meningococcal polysaccharide A,C,W and Y based vaccines.

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

This preparation has been tested against the original preparation of CDC1992 in standardised ELISA and was found to be equivalent in unitage. The total immunoglobulin, IgG, IgA and IgM antibody concentrations, assigned to CDC1992 are:

For serogroup A: 135.8, 91.8, 20.1 and 23.9 micrograms/ml respectively
For serogroup C: 32.0, 24.1, 5.9 and 2.0 micrograms/ml respectively
For serogroup Y: 38.4, 31.8, 3.7 and 2.9 micrograms/ml respectively
For serogroup W: 20.1, 16.2, 2.5 and 1.4 micrograms/ml respectively

4. CONTENTS

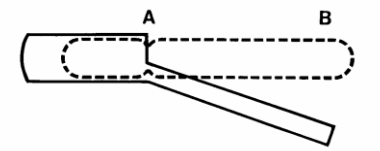
Country of origin of biological material: United Kingdom.
1ml freeze-dried CDC1992 human reference serum per ampoule.

5. STORAGE

Once rehydrated, the material should be aliquoted and stored at –20°C for no more than 6 months. Dispose of any material not used on the same day that it is thawed.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The contents of each ampoule should be rehydrated with 1ml sterile distilled water. Ensure that all material is resuspended, including any splashes around the neck of the ampoule

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

The antibody concentrations were correct at the time of manufacture – no information is available on long term stability. Stability of the reconstituted material should be determined by the user. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Holder P.K et al. Clin Diagn Lab Immunol 1995;2:132-7.
Elie C.M et al.. Clin Diagn Lab Immunol 2002;9:725-6.

10. ACKNOWLEDGEMENTS

George Carlone and collegues at CDC kindly donated this material to NIBSC. This reagent was previously supplied by Division of Bacterial and Mycotic Diseases, Centres for Disease Control and Prevention, Atlanta, USA who collected the serum pool and freeze-dried an aliquot of the frozen stock for distribution. The remainder of the serum was transferred to NIBSC in 1999 and the total amount was freeze-dried for distribution from January 2000

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

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.

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

Attached: No

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 yellow powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains material of human origin	
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: 4.5g.
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.**

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