



Non WHO Reference Material
Anti-meningococcal serogroup B monoclonal antibody
NIBSC code: 13/108
Instructions for use
(Version 1.0, Dated 12/09/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

For use as a typing reagent.

2. CAUTION

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

The preparation contains material of bovine origin that is certified to be obtained from animals taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE and which has not been fed rations containing ruminant derived protein during that period. 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

Units of activity have not been assigned to this material. Refer to Table on page 2 for recommended working concentrations.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Cell culture supernatant was purified by desalting and exchange into PBSA. The purified material was formulated to 2mg/ml in 25% fetal calf serum and RPMI medium. Each ampoule contains the freeze-dried powder from 1 ml of the final formulation.

5. STORAGE

Store freeze-dried ampoules and reconstituted aliquots 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.
Reconstitute the contents of each ampoule with 1 ml sterile distilled water. Ensure the entire content of each ampoule is fully resuspended.

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 recommended working 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

Granoff DM, Bartoloni A, Ricci S, Gallo E, Rosa D, Ravenscroft N, Guarnieri V, Seid RC, Shan A, Usinger WR, Tan S, McHugh YE, Moe GR. (1998). Bactericidal monoclonal antibodies that define unique meningococcal B polysaccharide epitopes that do not cross-react with human polysialic acid. J Immunol. 160(10):5028-36.

10. ACKNOWLEDGEMENTS

This material was produced from hybridoma cell line SEAM12 donated by Novartis Vaccines and Diagnostics, Italy, with permission from Childrens Hospital Oakland Research Institute, California.

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.

14. MATERIAL SAFETY SHEET

| Physical and Chemical properties | |
|--|---|
| Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified Physical appearance: Freeze-dried powder | Corrosive: No |
| | Stable: Yes |
| | Oxidising: No |
| | Hygroscopic: No |
| | Irritant: No |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): N/A | |
| 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 |
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| 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. |

reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

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|---|
| 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: 4.5 g |
| Toxicity Statement: Toxicity not assessed |
| Veterinary certificate or other statement if applicable. |
| Attached: No |

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

3. UNITAGE continued

| Specificity | Source of mAb ¹ | NIBSC hybridoma stock number ² | Isotype | Resuspension | Concentration of reconstituted stock to use in dot-blot ³ | Concentration of reconstituted stock to use in whole cell ELISA |
|--|----------------------------|---|--------------------|---|--|---|
| <i>Neisseria meningitidis</i> serogroup B polysaccharide | Granoff, DM. SEAM12 | 4137 | Mouse IgG2a, kappa | Each Din Ampoule should be resuspended with 1ml sterile distilled water | 1 in 50 | 1 in 200 |

Explanation of numbering system:

1. Source of mAb: The person in whose laboratory the hybridomas were isolated and their hybridoma clone designation.
2. NIBSC hybridoma stock number: this number was assigned at NIBSC when the hybridoma was received and is for NIBSC stock control only.
3. Determined by S.Gray Manchester Meningococcal Reference Unit