Non WHO Reference Material
Anti-meningococcal serosubtype P1.19 monoclonal antibody
NIBSC code: 04/248
Instructions for use
(Version 3.0, Dated 17/12/2013)

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. Each ampoule contains the freeze-dried powder from 1ml of cell culture supernatant concentrated approximately 60 fold. Antibody is of murine origin.

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.
Tap the ampoule gently to collect the material at the bottom (labelled) 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 new 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.
Each ampoule contains the freeze-dried powder from 1ml of cell culture supernatant concentrated approximately 60 fold. Resuspend each din ampoule with 1 ml sterile, distilled water. This reagent is for reference purposes only and is not intended for use as a routine serosubtyping reagent.

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

10. ACKNOWLEDGEMENTS
This material was produced from the hybridoma cell line number 7A2-11, provided by Dr W.D. Zollinger of the Walter Reed Army Institute of Research, Washington D.C., U.S.A.

11. FURTHER INFORMATION
Further information can be obtained as follows: This material: enquiries@nibsc.org
WHO Biological Standards: http://www.who.int/biologicals/en/
Derivation of International Units: http://www.nibsc.org/standardisation/international_standards.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
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 | |

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory
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
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.

Attached: No

3 Unitage continued

<table>
<thead>
<tr>
<th>Specificity</th>
<th>Source of mAb¹</th>
<th>NIBSC hybridoma stock number²</th>
<th>Resuspension</th>
<th>Titre by dot-blot³</th>
<th>Isotype</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serosubtype P1.19</td>
<td>Zollinger 2-1-P1.19</td>
<td>4050</td>
<td>The contents of 1 ampoule should be resuspended in 1ml water</td>
<td>1 in 250</td>
<td>IgG3</td>
</tr>
</tbody>
</table>

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 we received the hybridoma cells and is for NIBSC stock control only.
3. Determined by S.Gray Manchester Meningococcal Reference Unit.