Non WHO Reference Material
Meningococcal Capsular Group Y Polysaccharide
NIBSC code: 22/148

Instructions for use
(Version 1.0, Dated 04/08/2022)

This material is not for in vitro diagnostic use

1. INTENDED USE
This material is intended as a coating antigen used in standardised ELISA to detect anti-meningococcal capsular group Y antibody levels in human serum.

2. CAUTION
The material is not of human or bovine origin. This preparation is not for administration to humans or animals.

3. UNITAGE
When resuspended in 1ml of water the ampoule contains approximately 1 mg/ml capsular group Y polysaccharide.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains 1 mg freeze-dried meningococcal capsular group Y polysaccharide. Assigned content of vial valid at time of manufacture - no information on long term stability.

5. STORAGE
The contents of the ampoule should be rehydrated with sterile water to yield a stock solution of 1.0 mg/ml. Store in aliquots at -20°C and avoid excessive freeze-thawing.
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 preparation can be used for coating ELISA plates together with methylated human serum albumin (NIBSC reagent code 12/176).

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.
No information is available on long term stability of the material. 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
No references available

10. ACKNOWLEDGEMENTS
This material was kindly provided to NIBSC by GSK Vaccines S.r.l., Italy (formerly Novartis Vaccines) for distribution as a standard reagent.

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.biopharm.org/en-committees/jc/jc/tl/m/ 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
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>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td></td>
</tr>
<tr>
<td>Stable: Yes</td>
<td></td>
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<tr>
<td>Hygroscopic: No</td>
<td></td>
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<tr>
<td>Flammable: No</td>
<td></td>
</tr>
<tr>
<td>Other (specify): No special precautions</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
<tr>
<td>Net weight</td>
<td>4.5g</td>
</tr>
<tr>
<td>Toxicity Statement</td>
<td>Toxicity not assessed</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable</td>
<td>No</td>
</tr>
<tr>
<td>Attached</td>
<td>No</td>
</tr>
</tbody>
</table>