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 freezedried 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

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



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.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

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

(EC) No 1272/2008: Not applicable or not classified			
Physical and Chemical properties			
Physical appearance: Freeze dried powder		Corrosive:	No
Stable: Yes		Oxidising:	No
Hygroscopi No c:)	Irritant:	No
Flammable: No		Handling: See caution, Section 2	
Other No special precautions (specify):			
Toxicological properties			
Effects of inhalation: Not		established, avoid inhalation	
Effects of ingestion: Not		established, avoid ingestion	
Effects of		established,	avoid contact with
absorption:	skin		
Suggested First Aid			
Inhalation: Seek medical advice			
Ingestion: Seek medica		al advice	
Contact with Wash with copious amounts of water. Seek eyes: medical advice			
Contact with Wash thoroughly with water. skin:			





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