

# Non WHO Reference Material Anti-Meningococcal Serogroup A Monoclonal Antibody NIBSC code: 95/674 Instructions for use (Version 5.0, Dated 18/05/2023)

This material is not for in vitro diagnostic use

### 1. INTENDED USE

This reagent is for reference purposes only and is not intended for use as a routine serogrouping reagent.

### 2. CAUTION

This preparation is not for administration to humans or animals in the human food chain. The material is not of human or bovine origin. 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. Once reconstituted, the material should give a positive result in ELISA at a dilution of 1:100.

### 4. CONTENTS

Country of origin of biological material: United Kingdom. Each ampoule contains the freeze-dried powder from 1ml of a 1 in 50 dilution of ascitic fluid in phosphate-buffered saline. Antibody is of murine origin.

### 5. STORAGE

The reconstituted material should be aliquoted and frozen 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 freezedried material prior to reconstitution

Resuspend the contents of the ampoule in 1ml of 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 concentration was 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 is the residue from freeze-drying of ascitic fluid collected from pristane-treated mice after intra-peritoneal injection with cells of the hybridoma cell line 2D7B5B5B2, 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/

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 of flot classified		
Physical and Chemical properties		
Physical appearance:	Corrosive:	No
Freeze dried powder		
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.		

# NIBSC Confidence in Biological Medicines

### **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 freezedrying.

Net weight: 4.5g.

**Toxicity Statement: Toxicity not assessed** 

Veterinary certificate or other statement if applicable.

Attached: No