

**Non WHO Reference Material**  
**Anti-Meningococcal Serotype P3.4 Monoclonal Antibody**  
**NIBSC code: 02/308**  
**Instructions for use**  
**(Version 5.0, Dated 01/11/2018)**

**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 24 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. 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**  
Resuspend each din ampoule with 1 ml 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.

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Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, [nibsc.org](http://nibsc.org)  
WHO International Laboratory for Biological Standards,  
UK Official Medicines Control Laboratory

**9. REFERENCES**

**10. ACKNOWLEDGEMENTS**

This material was produced from the hybridoma cell line 5DC4C8G8 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](mailto: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](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](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](mailto: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 and Chemical properties			
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
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.

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**

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 4.5g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> 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](http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx) or upon request by the Recipient) ("Conditions") apply to the exclusion of all

**3. UNITAGE continued**

The material has been tested for use in whole cell dot-blot and whole-cell ELISA as follows:

Explanation of numbering system:

Specificity	Source of mAb <sup>1</sup>	Isotype	NIBSC hybridoma stock number <sup>2</sup>	Resuspension	Concentration of reconstituted stock to use in Dot-blot	Concentration of reconstituted stock to use in whole-cell ELISA
Meningococcal serotype P3.4	Zollinger 5DC4C8G8	IgG2b	4058	Each ampoule should be re-suspended in 1ml distilled water	1 in 500	1 in 100

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.