



**Non WHO Reference Material**  
**Anti-meningococcal serogroup Y monoclonal antibody**  
**NIBSC code: 12/284**  
**Instructions for use**  
**(Version 2.0, Dated 12/06/2019)**

**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.**

Antibody is of murine origin. The material 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. However, when used for whole-cell dot blot, a dilution of 1 in 50 of the reconstituted material is recommended. Refer to Table on page 2.

**4. CONTENTS**

Country of origin of biological material: United Kingdom.  
Ascitic fluid purified by 50% Ammonium sulfate cut then DEAE ion exchange in to a final buffer of 20mM Na phosphate/ 150mM NaCl. Purified ascites were diluted with RPMI tissue culture medium and 25% fetal calf serum before freeze-drying.

**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.**

The entire content of the ampoule should be rehydrated with 1 ml of sterile water.

**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. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

**9. REFERENCES**

N/A

**10. ACKNOWLEDGEMENTS**

We are grateful to Pfizer Vaccine Research, USA for providing purified ascitic fluid from hybridoma PFEMnY.

**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](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

**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**

Physical and Chemical properties	
<b>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified</b> 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.

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> 4.5 g
<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 other terms and are hereby incorporated into this document by

**Explanation of numbering system:**

1. Source of mAb: The laboratory where the hybridoma was 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

Specificity	Source of mAb <sup>1</sup>	NIBSC hybridoma stock number <sup>2</sup>	Isotype	Resuspension	Concentration of reconstituted stock to use in dot-blot <sup>3</sup>
<i>Neisseria meningitidis</i> serogroup Y polysaccharide	Pfizer Vaccine Research, USA. PFEMnY	N/A	Mouse IgG1, kappa	Each Din Ampoule should be resuspended with 1ml sterile distilled water	1 in 50