Medicines & Healthcare products Regulatory Agency



Working Standard Anti-pneumococcal serotype 15B monoclonal antibody (clone 2F4) NIBSC code: 22/278 Instructions for use

(Version 1.0, Dated 07/03/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody 22/278 (Clone 2F4) is intended for use as a serotyping reagent. It is suitable for use in a variety of immunoassays for the detection and quantification of pneumococcal capsular polysaccharide 15B (Pn15B).

2. CAUTION

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

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

N/A

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial contains 0.5 mL of liquid anti-pneumococcal serotype 15B monoclonal antibody at a total protein concentration of 1 mg/mL. 22/278 is a murine IgG1 kappa antibody produced from hybridoma. The hybridoma was produced using a purified Pn15B specific polysaccharide conjugate for the immunisation of mice. The antibody is in Phosphate Buffer pH 7.3.

Batch 1 (Bulk batch ID PH2/PATH/22/015)

5. STORAGE

The material should be stored between -20°C and -80°C Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

22/278 has been used in a sandwich ELISA for detection of Pn15B. The most suitable dilution for use of this antibody should be determined by the end user for their specific application.

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.

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

9. REFERENCES

This section will be updated when references are made available.

10. ACKNOWLEDGEMENTS

We are grateful to PATH, USA for collaborating with NIBSC and for funding this work to make available a panel of pneumococcal monoclonal antibodies. PATH is a global, non-profit organisation working towards improving public health.

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/jctIm/ 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

Physical and Chemical properties				
Physical appearance:		Corrosive:	No	
Liquid				
Stable: Yes		Oxidising:	No	
Hygroscopi No		Irritant:	No	
с:				
Flammable: No		Handling: S	ee caution, Section 2	
Other None				
(specify):				
Toxicological properties				
Effects of inhalation:	Not e	established, avoid inhalation		
Effects of ingestion:	Not e	established, avoid ingestion		
Effects of skin	Not	established,	avoid contact with	
absorption:	skin			
Suggested First Aid				
Inhalation: Seek medical advice				
Ingestion: Seek medical advice				
Contact with Was	ct with Wash with copious amounts of water. Seek			
eyes: med	eyes: medical advice			
Contact with Was	with Wash thoroughly with water.			
skin:				
Action on Spillage and Method of Disposal				
Spillage of ampoule contents should be taken up with				

Splitage 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.

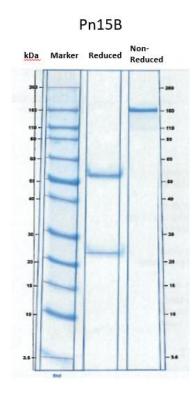
16. INFORMATION FOR CUSTOMS USE ONLY

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: 0.5 g		
Toxicity Statement: Non-toxic		
Veterinary certificate or other statement if applicable.		
Attached: No		



Additional product information for this batch

SDS PAGE:



Purity by HPLC: 99%