Working Standard
Anti-pneumococcal serotype 18C monoclonal antibody
NIBSC code: 21/290
Instructions for use
(Version 1.0, Dated 21/12/2022)

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody 21/290 (Clone 15-104AG5 IIH4) 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 18C (Pn18C).

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 States.

Each vial contains 0.5 mL of liquid anti-pneumococcal serotype 18C monoclonal antibody at a total protein concentration of 1 mg/mL. 21/290 is a murine lgG1 lambda antibody produced from hybridoma and purified by mabSelect. The hybridoma was produced using a purified Pn18C specific polysaccharide conjugate for the immunisation of mice. The antibody is in Phosphate Buffer pH 7.2.

Batch 1 (Bulk batch ID F15702)

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

21/290 has been used in a sandwich ELISA for detection of Pn18C. 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.



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/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.



Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

14. MATERIAL SAFETY SHEET

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

(EC) No 12/2/2008: Not applicable or not classified				
Physical and Chemical properties				
Physical appea Liquid	rance:	Corrosive:	No	
Stable:	Yes	Oxidising:	No	
Hygroscopi c:	No	Irritant:	No	
Flammable:	mable: No		Handling: See caution, Section 2	
Other (specify):	None			
Toxicological properties				
Effects of inhalation: Not		established, avoid inhalation		
Effects of ingestion: No		t established, avoid ingestion		
Effects of absorption:	skin Not skir		avoid contact with	
Suggested First Aid				
Inhalation: Seek medical advice				
Ingestion: Seek medica		cal 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 States

* 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

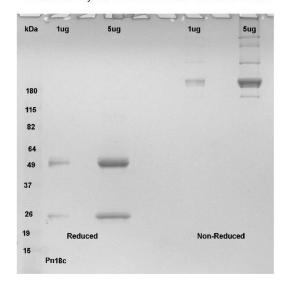
Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No

Additional product information for this batch





% Aggregation by size exclusion chromatography: >20%