Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Anti-pneumococcal polysaccharide monoclonal antibodies
NIBSC code: 21/268 - 21/294 even nos.
Instructions for use
(Version 1.0, Dated 05/11/2021)

This material is not for in vitro diagnostic use.

1. INTENDED USE

NIBSC codes: 21/268, 21/270, 21/272, 21/274, 21276, 21/278, 21/280, 21/282, 21/284, 21/286, 21/288, 21/290, 21/292, 21/294. Please see table on page 2 for seortype specificity.

The materials may be used as typing reagents and in a variety of other assays including the detection of capsular polysaccharide by enzyme-linked immunosorbent assay, with multiplexed immunoarrays or rate nephelometry.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

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. The optimal antibody concentration which gives the best signal with minimum background, must be determined experimentally for each assay and is usually determined by using a series of dilutions in a titration experiment.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial contains approximately 0.5 mg (0.5 ml) antibody formulated in PBS, pH 7.3-7.5 (the final pH of each formulation has not been determined). The antibody was purified after expression from a hybridoma cell line. Please refer to the table on page 2 for additonal details.

5. STORAGE

Store the unopened vial and and aliquoted material at -20. Avoid freeze-thaw cycles.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

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

It is recommended that aliquots of the material are made to minimise freeze-thaw cycles.

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.

No information is available on long term stability. Stability should be determined by the user. Customers who have data supporting any deterioration in the characteristics of any reference material are encouraged to contact NIBSC.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

This section will be unpdated when references are made available. The updated IFU will be published on the NIBSC product catalogue section of the website, www.nibsc.org, in due course.

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.

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: Clear liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):			

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

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

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.

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: Toxicity not assessed

Veterinary certificate or other statement if applicable**.**
Attached: No

Catalogue no.	Serotype specificity	Product name	Isotype	Hybridoma
21/268	1	Anti-pneumococcal serotype 1 monoclonal antibody	IgG1 kappa	13-110A
21/270	3	Anti-pneumococcal serotype 3 monoclonal antibody	IgG1 kappa	15-103FC11 IH5
21/272	5	Anti-pneumococcal serotype 5 monoclonal antibody	IgG1 kappa	1366LC1 IE11
21/274	6A/6C	Anti-pneumococcal serotype 6A / 6C monoclonal antibody	IgG1 kappa	14-107JG10 IA1/IB1 IIG10
21/276	7F	Anti-pneumococcal serotype 7F monoclonal antibody	IgG1 kappa	15-102HG6 ID8
21/278	8	Anti-pneumococcal serotype 8 monoclonal antibody	IgG1 kappa	7D3
21/280	9N	Anti-pneumococcal serotype 9N monoclonal antibody	IgG1 kappa	18-125BG4 ID4
21/282	9V	Anti-pneumococcal serotype 9V monoclonal antibody	IgG2a	15-112EG9 IE2
21/284	10A	Anti-pneumococcal serotype 10A monoclonal antibody	IgG1 kappa	17-117IA3 IIB6
21/286	12F	Anti-pneumococcal serotype 12F monoclonal antibody	IgG1 kappa	1C1
21/288	14	Anti-pneumococcal serotype 14 monoclonal antibody	IgG2a kappa	13-111A
21/290	18C	Anti-pneumococcal serotype18C monoclonal antibody	IgG1 lambda	15-104AG5 IIH4
21/292	19A	Anti-pneumococcal serotype 19A monoclonal antibody	IgG1 kappa	14-105IH8 IE12
21/294	22F	Anti-pneumococcal serotype 22F monoclonal antibody	IgG1 kappa	17-122 CG1 IC3