Working Standard
Anti-pneumococcal serotype 35B monoclonal antibody (clone 3F9)

NIBSC code: 22/308

Instructions for use
(Version 1.0, Dated 07/03/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE
Monoclonal antibody 22/308 (Clone 3F9) 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 35B (Pn35B).

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 35B monoclonal antibody at a total protein concentration of 1 mg/mL. 22/308 is a murine IgG2b kappa antibody produced from hybridoma. The hybridoma was produced using a purified Pn35B specific polysaccharide conjugate for the immunisation of mice. The antibody is in Phosphate Buffer pH 7.3.

Batch 1 (Bulk batch ID KP17082)

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
22/308 has been used in a sandwich ELISA for detection of Pn3SB. 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.
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 |
| Stable: | Yes | Oxidising: | No |
| Hygroscopic: | No | Irritant: | No |
| Flammable: | No | Handling: See caution, Section 2 |

Other (specify): None

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.

15. LIABILITY AND LOSS
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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

Purity by SDS PAGE: >95%

Aggregation by size exclusion chromatography with multi-angle light scattering: 0%

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory