Working Standard
Pertussis Toxoid Monoclonal Antibody PS21C2.2.1
NIBSC code: PS21C2.2.1
Instructions for use
(Version 2.0, Dated 23/08/2022)

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody clone PS21C2.2.1 is intended to be used in immunoassays that measure the content and quality of pertussis toxoid antigen in vaccines for human use.

Batch 1 (Batch ID 220221-PS21)

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: France.

Each vial contains 0.5 ml of liquid anti-pertussis toxoid monoclonal antibody clone PS21C2.2.1 at a total protein concentration of 1 mg/mL. PS21C2.2.1 is a mouse lgG1 antibody produced from hybridoma and Protein A purified. The antibody is in Phosphate Buffer pH 7.4 (155 mM NaCl, 50 mM Na $_2$ HPO $_4$ and 1.8 mM KH $_2$ PO $_4$). The antibody was filtered (0.2 μ M) and does not contain preservative.

5. STORAGE

The material should be stored in the dark at -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

PS21C2.2.1 is directed against the S1 subunit of pertussis toxoid and can be paired with monoclonal antibody 629E1 in immunoassays requiring both a capture and detection antibody.

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

None

10. ACKNOWLEDGEMENTS

N/A

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

(EC) No 1272/2008: Not a	applic	able or not cla	ssified
Physical and Chemical properties			
Physical appearance: Liquid		Corrosive:	No
Stable: Yes		Oxidising:	No
Hygroscopi No c:		Irritant:	No
Flammable: No		Handling: Se	ee caution, Section 2
Other None (specify):			
Toxicological properties			
Effects of inhalation: Not e		established, a	void inhalation
Effects of ingestion: Not		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 Wash with copious amounts of water. Seek			
eyes: medical advice			
Contact with Wash skin:	thoro	ughly with wa	nter.
Action on Spillage and Method of Disposal			
Chillago of amnoula contents abould be taken up with			

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*: France
* 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

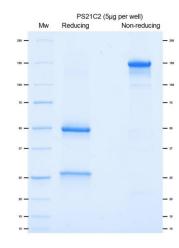
Veterinary certificate or other statement if applicable.

Attached: No

17. ADDITIONAL PRODUCT INFORMTION FOR THIS BATCH

SDS-PAGE profile for PS21C2.2.1:





SE-HPLC chromatogram for PS21C2.2.1:

