



Non WHO Reference Material
Bordetella pertussis Anti-Agglutinin 2 (rabbit)
NIBSC code: 89/598
Instructions for use
(Version 7.0, Dated 09/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is a polyclonal rabbit antiserum to *Bordetella pertussis* agglutinin 2 rendered specific by cross-absorption. It is intended for detection of agglutinin (serotype) specific antigens in whole cell pertussis vaccines.

2. CAUTION

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

The material is not of human or bovine origin. 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

No unitage is assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried residue of 0.5ml of 0.01M sodium phosphate pH 7.4, 0.15M NaCl which contained diluted rabbit antiserum to *Bordetella pertussis* serotype 2 after cross-absorption to remove antibodies reactive with heat-labile antigens.

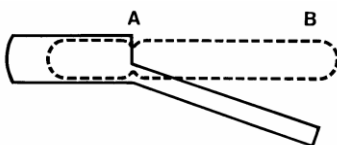
5. STORAGE

Unopened ampoules should be stored at -20°C.

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

7. USE OF MATERIAL

For practical purposes each ampoule contains the same quantity of serum. The entire contents of each ampoule should be completely dissolved in an accurately measured amount of solvent (distilled water,

saline, or buffer) and the solution kept cool (+4°C) prior to use. No attempt should be made to weigh out proportions of the freeze dried powder. It is recommended that for this preparation, the contents should be dissolved in 0.5ml of sterile distilled water.

It is recommended that the solution, not for immediate use, is stored at -20°C or below. Repeated freezing and thawing should be avoided. The ampoules contain no bacteriostat and the preparations should not be assumed to be sterile.

Rabbit antiserum to *B. pertussis* strain 360 E which expresses agglutinin 2 was prepared by repeated immunisation. The serum was absorbed with autoclaved *B. pertussis* cells and with formaldehyde-treated cells of *B. pertussis* strains GL353 and 134 to remove cross-reactive agglutinins. The specificity of the serum was checked by agglutinin assays and at the recommended concentration produces clear agglutination with *B. pertussis* strains of serotype 1,2 but not serotype 1 and 3. It has been evaluated in an international collaborative study involving laboratories in China, Holland, New Zealand, and the United Kingdom.

The ampoules coded 89/598 were prepared according to the procedures specified for International Biological Standards (29th ECBS Report 1978). The absorbed serum was diluted 1:50 in phosphate buffered saline, pH 7.4 and sterilised by membrane filtration. It was distributed in 0.5 ml volumes into ampoules and lyophilised. The ampoules were then sealed under nitrogen by heat fusion of the glass and stored at -20°C in the dark.

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.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Preston N.W. 1970 Laboratory Practice 19,482-486

10. ACKNOWLEDGEMENTS

Grateful acknowledgement is due to Standards Processing Division for the filling.

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: Freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of rabbit origin.
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

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