



**Non WHO Reference Material
Anti-Bordetella pertussis serum (Human)
NIBSC code: 89/530
Instructions for use
(Version 5.0, Dated 10/04/2013)**

This material is not for in vitro diagnostic use.

1. INTENDED USE

This NIBSC Reference Reagent for Pertussis Antiserum, human, has been prepared from a pool of sera from individuals who had recently recovered from pertussis infection or been vaccinated. It is intended for use in ELISA or IRMA assays for measurement of anti-*B. pertussis* antibodies in human serum.

2. CAUTION

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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

Each ampoule contains 110 units of anti-FHA, and 120 units of anti-69kD. Information about anti-FIM 2 and anti-FIM 3 separately is not available. Nevertheless 280 units of anti-FIM 2&3 represents a consistent consensus for the mixture obtained in the collaborative study in terms of the mixture in US lot 3 which has taken to be 100 units. No anti-PT unitage can be recommended on the basis of the collaborative study, and use of this preparation for anti-PT would therefore require calibration in the individual assay system.

4. CONTENTS

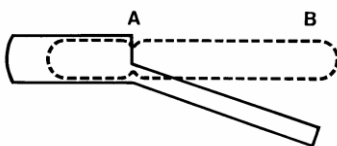
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried residue of 0.5ml of serum.

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 antiserum. The entire contents of each ampoule should be completely dissolved in an accurately measured amount of distilled water 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 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.

The human antiserum was prepared from blood from each of 3 members of staff who had been immunised with five component acellular pertussis vaccine and from each of 2 adults who had recovered from whooping cough. These sera were heated at 60°C for 30 min and tested in ELISAs for anti-pertussis antibodies. These sera were then pooled to yield a total volume of 800 ml which was diluted to 1600 ml by addition of pyrogen-free saline. This two fold diluted serum pool was then dispensed in 0.5 ml aliquots into glass ampoules, coded 89/530, and freeze-dried under vacuum, sealed and stored at -20°C in the dark.

COLLABORATIVE STUDY

Six laboratories in five countries participated in the collaborative study to evaluate 89/530. The study showed:-

Calibration of this material in terms of US Lots 3 and 4 gave results which were broadly consistent between laboratories for antibodies to FHA, 69kD and FIMS 2&3 but which were less consistent for antibodies to PT and therefore no anti-PT unitage has been recommended on the basis of this study.

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. They remain valid with the assigned potency and status until withdrawn or amended.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

The collaborative study report is available on request from NIBSC (See Section 11)

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Drs. Bruce Meade and Juan Arciniega, Center for Biologics Evaluation and Research, FDA, Rockville, MD, USA for provision of ampoules of US Standard Pertussis Antiserum, Human, Lots 3 & 4. We also thank all of the participants for their helpful contributions to the collaborative study and 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 human 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