Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Bordetella pertussis anti - FHA serum (sheep)
NIBSC code: 97/564
Instructions for use
(Version 5.0, Dated 10/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The antiserum was prepared in a sheep to purified *Bordetella pertussis* filamentous haemagglutinin and for the purposes of use in control testing of acellular 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 vial contains the freeze-dried residue of 1.0ml of 0.01M potassium phosphate pH7.2, 0.5M NaCl solution which contained immunoglobulin purified by precipitation of anti- *Bordetella pertussis* FHA serum with 50% saturated ammonium sulphate.

5. STORAGE

Unopened vials 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

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

For practical purpose each vial contains the same quantity of the antiserum. The entire contents of each vial should be completely resuspended in an accurately measured amount of water or buffer solution. No attempt should be made to weigh out proportions of the freeze-dried powder.

It is recommeded that the suspension, if not for immediate use, is stored at –20°C or below. Repeated freezing and thawing should be avoided. The vials contain no bacteriostat and the preparation should not be assumed to be sterile.

The antigen used for immunisation of the sheep was purified filamentous haemagglutinin which was generously donated by SmithKline Beecham Pharmaceuticals, Rixensart, Belgium through the good offices of Dr M Duchene. One dose of 250µg of antigen in phosphate buffered saline (PBS) emulsified with Freund's complete adjuvant (FCA) in a total volume of 2ml was given intramuscularly to the sheep, followed by three doses of 150µg of the antigen at four week intervals. Terminal bleed was carried out 2 weeks after the last injection. The serum was partially purified by precipitation of immunoglobulin with 50% saturated ammonium sulphate. The precipitate was resusupended in PBS and the suspension was distributed in 1ml aliquots into vials and lyophilised. The reactivity of antiserum against homologous antigen and cross reaction with other pertussis antigens was checked by ELISA.

At a dilution of 1/10,000 the antiserum gave homologous titres and no cross-reaction to other pertussis antigens.

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

N/A

10. ACKNOWLEDGEMENTS

Grateful acknowledgement are due to: Dr Dr M. Duchene and SmithKline Beecham Pharmaceuticals for providing the material, 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

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

Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains dired material of sheep 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 vial 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: 1.0 - 2.0 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No