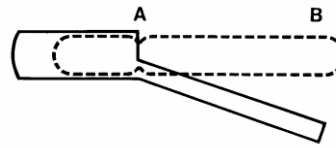




**Non WHO Reference Material
Botulinum type A antitoxin, equine
NIBSC code: 59/021
Instructions for use
(Version 6.0, Dated 05/03/2013)**

This material is not for in vitro diagnostic use.



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.

1. INTENDED USE

This material is a freeze-dried residue of horse antiserum to Clostridium botulinum type A toxin. It is intended for calibration of the bioassay for botulinum type A antitoxin. The material may also be suitable to confirm serotype identity of botulinum type A toxin. It has recently been reported that no cross-neutralisation with botulinum toxin serotypes C1, D, E, F or G is found with a large excess of this antitoxin in the mouse lethal assay. However, cross-neutralisation with type B toxin was seen. This has now been independently confirmed at NIBSC using an in vivo local flaccid paralysis assay with cross-neutralisation of type B toxin seen at a thousand-fold or greater excess of antitoxin (59/021).

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

This material is a candidate replacement for the 1st International Standard for botulinum type A antitoxin (BTUSA or 60/18). Full calibration has yet to be performed in collaborative studies. Preliminary tests at NIBSC have indicated 2,000 IU/ampoule by local flaccid paralysis assay relative to the 1st WHO International Standard (60/18).

4. CONTENTS

Country of origin of biological material: United Kingdom.
The bulk material was donated in 1959 by Burroughs, Wellcome (Beckenham, UK). The hyperimmune serum was diluted with 8 parts of normal horse serum to give 2,000 Units/ml, then filled and freeze dried, overlaid with nitrogen and sealed in ampoules at the National Institute for Medical Research, London (UK) in 1960 as a reserve batch. This preparation contains the freeze-dried residue of 1.0 ml of horse 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.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

Clostridium botulinum antitoxins were established to define International Units for each type of antitoxin to be used in the control of therapeutic antitoxin preparations. Preparation and assay of the International Standard for Clostridium botulinum types A, B, C, D and E antitoxin were described by Bowner [1]. This material, as replacement for BTUSA, is intended for calibration of the bioassay for botulinum type A antitoxin. The material may also be suitable to confirm type A serotype identity.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated.

Units assigned to this material were valid at the time of calibration and there is no data available on long term stability. However, freeze-dried serum standards are expected to undergo negligible loss of activity during long term storage at the indicated storage temperature [2].

Once reconstituted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any changes in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

1. Bowner EJ. Preparation and assay of the International standards for Clostridium botulinum types A, B, C, D and E antitoxins. Bull World Health Organization 1963, 29, 701-709.
2. Jerne NK and Perry WLM. The Stability of Biological Standards, Bull. Wld. Hlth. Org. 1956, vol. 14 pp 167-182.
3. Jones RGA, Corbel MJ. & Sesardic D. A review of WHO International Standards for botulinum antitoxins. Biologicals 2006, 34, 223-226.

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

Physical and Chemical properties	
Physical appearance: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains equine serum
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: Approx 100mg

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No