



**Non WHO Reference Material  
Botulinum type D antitoxin, equine  
NIBSC code: 01/510  
Instructions for use  
(Version 6.0, Dated 24/01/2014)**

**This material is not for in vitro diagnostic use.**

**1. INTENDED USE**

This material is a freeze-dried residue of horse antiserum to Clostridium botulinum type D toxin complex. It is intended for calibration of the bioassay for botulinum type D antitoxin. The material may also be suitable to confirm serotype identity of botulinum type D toxin / toxoid.

**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 61/001 (BTUSD). Calibration has yet to be performed.

**4. CONTENTS**

Country of origin of biological material: United States.  
This preparation contains the freeze-dried residue of 1.0 ml of horse plasma. The material was donated to NIBSC in July 1998 by the US Army Medical Research Institute of Infectious Diseases, Fort Detrick, USA. The material was made by immunising horses with Botulinum type D toxoid followed by toxin complex (from strain D CB-16) and plasma obtained at week 64. This material has yet to be calibrated against the 1<sup>st</sup> WHO International Standard 61/001 (BTUSD).

**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**

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

**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 1<sup>st</sup> International Standard for Clostridium botulinum types A, B, C, D and E antitoxin were described by Bowner [1]. This material, as a candidate replacement for 61/001 (BTUSD), is intended for calibration of the bioassay for botulinum type D antitoxin. The material may also be suitable to confirm serotype identity of botulinum type D toxin / toxoid.

**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.

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**

We would like to thank USAMRIID for kindly donating this material.

**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](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](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:<br>Yes  | Oxidising: No                    |
| Hygroscopic:<br>Yes   | Irritant: No                     |
| Flammable:<br>No  | Handling: See caution, Section 2 |
| Other (specify): Contains horse plasma  |                                  |
| <b>Toxicological properties</b>   |                                  |
| Effects of inhalation: Not established, avoid inhalation  |                                  |
| Effects of ingestion: Not established, avoid ingestion  |                                  |
| Effects of skin absorption: Not established, avoid contact with skin  |                                  |
| <b>Suggested First Aid</b>  |                                  |
| 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.  |                                  |
| <b>Action on Spillage and Method of Disposal</b>  |                                  |
| 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](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

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|---|
| <b>Country of origin for customs purposes*:</b> United Kingdom<br>* 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. |
| <b>Net weight:</b> Approx 100mg   |
| <b>Toxicity Statement:</b> Non-toxic  |
| <b>Veterinary certificate or other statement</b> if applicable.<br><b>Attached:</b> No  |