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.

1. INTENDED USE
This material is a freeze-dried residue of horse antiserum to Clostridium botulinum type A antitoxin. It has been 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.

2. UNTAGE
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).

3. 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.

4. STORAGE
Unopened ampoules should be stored at -20ºC.

5. 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 opening. 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.

6. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

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

8. REFERENCES

9. ACKNOWLEDGEMENTS
N/A

10. 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

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

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.
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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th></th>
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<tbody>
<tr>
<td><strong>Physical appearance</strong>: Freeze dried powder</td>
<td>Corrosive: No</td>
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<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
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<tr>
<td>Hygroscopic: Yes</td>
<td>Irritant: No</td>
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<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Contains equine serum</td>
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</tbody>
</table>

**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 |
| Veterinary certificate or other statement if applicable. Attached: No |
| Net weight: Approx 100mg |
| Toxicity Statement: Non-toxic |

* 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.

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