Non WHO Reference Material
Botulinum type E antitoxin, equine
NIBSC code: 02/318
Instructions for use
(Version 5.0, 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 E toxin complex. It is intended for calibration of the
bioassay for botulinum type E antitoxin. The material may also be suitable
to confirm serotype identity of botulinum type E 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 the 1st International Standard
for botulinum type E antitoxin (BTUSE or 60/023). Full calibration has yet
to be performed in collaborative studies. Preliminary tests at NIBSC have
indicated 197 IU/ampoule by local flaccid paralysis assay relative to the 1st
WHO International Standard (BTUSE).

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 bulk material was donated in 1998 by the US Army Medical
Research Institute of Infectious Diseases, Fort Detrick, Frederick, MD,
USA, with nominal activity of ca. 166 IU/ml. Horses were immunised with
toxoid (complex from strain E1 German sprats) followed by toxin (complex
from E1 German sprats and E3 Alaska E43) and plasma obtained after 36
weeks.

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 1st International
Standard for Clostridium botulinum types A, B, C, D and E antitoxin were
described by Bowner [1]. This material, as replacement for BTUSE, is
intended for calibration of the bioassay for botulinum type E antitoxin. The
material may also be suitable to confirm type E 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 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

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/tlm/
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
referred, 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>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
</tr>
</tbody>
</table>

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory
<table>
<thead>
<tr>
<th>Hygroscopic:</th>
<th>Yes</th>
<th>Irritant:</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable:</td>
<td>No</td>
<td>Handling:</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Contains equine plasma</td>
<td></td>
<td></td>
</tr>
</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**

<table>
<thead>
<tr>
<th>Inhalation:</th>
<th>Seek medical advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion:</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Contact with eyes:</td>
<td>Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td>Contact with skin:</td>
<td>Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*:</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
<tr>
<td>Net weight:</td>
<td>Approx. 100mg</td>
</tr>
<tr>
<td>Toxicity Statement:</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable:</td>
<td>Attached: No</td>
</tr>
</tbody>
</table>