Non WHO Reference Material

Diphtheria Antitoxin for the Flocculation Test, 4th British Reference Preparation (Est. 1963)
NIBSC code: 63/007

Instructions for use (Version 7.0, Dated 29/11/2012)

This material is not for in vitro diagnostic use.

1. INTENDED USE
This material is the freeze dried residue of hyperimmune horse antiserum to diphtheria toxoid/toxin. It is intended for use as a reagent in the in vitro flocculation (Lf) assay for diphtheria toxoid. When used in the flocculation assay, the Lf equivalent value must be determined in-house [1].

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
Each ampoule contains 1300 International Units (IU) of diphtheria antitoxin as determined by in vivo toxin neutralisation test.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze dried residue of approximately 1 ml of horse serum diluted with an equal volume of distilled water.

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 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.

A
B

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.

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

The entire contents of each ampoule should be completely dissolved in 2 ml of sterile distilled water. The resulting concentrate may be diluted with saline to give a total volume of 13 ml containing 100 IU of diphtheria antitoxin per ml. The ampoules contain no bacteriostat and the preparations should not be assumed to be sterile.

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.

Dried serum standards are expected to undergo negligible loss of potency 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 deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

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

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

| 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 |
| Toxicity Statement: Non-toxic |
| Net weight: 2 ml |
| Veterinary certificate or other statement if applicable. Attached: No |