Non WHO Reference Material
Diphtheria Polyclonal Antibody
NIBSC code: 10/128
Instructions for use
(Version 4.0, Dated 17/01/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE
Diphtheria polyclonal antibody is intended to be used as a detecting antibody in ELISA to measure diphtheria antigen. For examples of use of the assay, see reference [1].

2. CAUTION
This preparation is not for administration to humans or animals in the human food chain.

Human serum albumin used in formulation contains material of human origin which has been tested and confirmed negative for viral markers. 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
N/A

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains 0.5 ml of freeze-dried diphtheria antiserum formulated in PBS with 0.5% human serum albumin and 0.1% trehalose. The antiserum was prepared from guinea pigs immunised with 1/2 single human dose (SHD) of monovalent diphtheria vaccine (adsorbed), and boosted 4 weeks later with 1/5 SHD of monovalent diphtheria vaccine (adsorbed). Guinea pigs were bled and serum harvested 2 weeks after boosting.

5. STORAGE
Unopened ampoules should be stored in the dark 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.
The entire contents of each ampoule should be completely resuspended in an accurately measured amount of suitable solution (e.g. purified water). An appropriate working dilution is 1/200 (diluted in a suitable buffer for assay) after resuspending each ampoule in 0.5 ml. However, it is recommended to optimise the reagent in-house for specific application.

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.
Freeze-dried serum standards are expected to undergo negligible loss of activity during long term storage at the indicated storage temperature [2].
Long term storage after reconstitution (at +4°C or frozen) is yet to be established. 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

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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance:</td>
<td>Freeze-dried powder</td>
</tr>
<tr>
<td>Corrosive:</td>
<td>No</td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
</tr>
<tr>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>Yes</td>
</tr>
<tr>
<td>Irritant:</td>
<td>No</td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
</tr>
<tr>
<td>Handling:</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>None</td>
</tr>
</tbody>
</table>

**Toxicological properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of inhalation:</td>
<td>Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion:</td>
<td>Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption:</td>
<td>Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>

**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
- **Net weight**: 0.5 g
- **Toxicity Statement**: Non-toxic
- **Veterinary certificate or other statement**: if applicable, Attached: No