Non WHO Reference Material
Anti-PT S1 subunit Monoclonal Antibody E1E
NIBSC code: 99/516
Instructions for use
(Version 5.0, Dated 05/05/2015)

This material is not for in vitro diagnostic use.

1. INTENDED USE
Material E1E is a monoclonal antibody which reacts to pertussis toxin S1 subunit. The hybridoma cell line for the production of the monoclonal antibody was established by Drs H. Sato and Y. Sato, National Institute of Infectious Diseases, Tokyo, Japan.

It is intended for use as a research reagent to characterise pertussis toxin.

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
No unitage is assigned to this material.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each vial contains 400 µl of frozen material from mouse ascitic fluid. The monoclonal antibody was prepared from pristane-treated mice after intraperitoneal injection with cells of the hybridoma cell line E1E. The ascitic fluid was diluted 1/25 in PBS containing 1% normal mouse serum. This solution was dispensed in 400 µl aliquots into vials, coded 99/516 and stored at -20°C in the dark.

5. STORAGE
It is recommended that unopened vials, aliquots and diluted material not for immediate use, are stored at -20°C or lower. Repeat freeze-thawing should be avoided. The vials contain no bacteriostat and the preparation should not be assumed to be sterile.

6. DIRECTIONS FOR OPENING
Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL
A suggested dilution of approximately 1/500 of this solution is recommended for the initial dilution on the ELISA plate. However, this may vary with individual laboratories.

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. They remain valid with the assigned potency and status until withdrawn or amended.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

10. ACKNOWLEDGEMENTS
Grateful acknowledgements are due to Dr H Sato, National Institute of Infectious Diseases, Tokyo, Japan for the kind donation of the hybridoma cell line.

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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Liquid</td>
<td></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>No</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>Contains material of mouse 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 vial 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>
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</thead>
</table>

* 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.

<table>
<thead>
<tr>
<th>Net weight:</th>
<th>0.4 g</th>
</tr>
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<tbody>
<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>

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