Non WHO Reference Material
Bordetella pertussis, (W28) LPS (2µg)
NIBSC code: 89/594
Instructions for use
(Version 6.0, Dated 10/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE
This material is an extract of B. pertussis (W28) cells. The preparation is a candidate reference preparation for use in LAL gelation tests, and rabbit pyrogen tests.

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 ampoule contains 2 micrograms B.pertussis W28 LPS and 3 mg trehalose.

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 file or other suitable implement before attempting to open. 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.

7. USE OF MATERIAL
The lipopolysaccharide fraction of B. pertussis strain Wellcome 28 was extracted by a standard method employing warm phenol-water and further purified by proteinase K digestion followed by heat inactivation. The ampoules coded (89/594) were prepared according to the procedures used for International Biological Standards (29th ECBS Report, WHO 1978). The ampouled solution was lyophilised and the ampoules sealed under nitrogen by heat fusion of the glass and stored at –20°C in the dark. Reconstitute contents of an ampoule by adding a known volume of solvent (pyrogen free distilled water, saline or buffer), mix thoroughly. The reconstituted material should be stored at -20°C. No attempt should be made to weigh out proportions of the freeze dried powder. The ampoules contain no bacteriostat and the preparation 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. 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
N/A

10. ACKNOWLEDGEMENTS
Grateful acknowledgements are due to Standards Processing Division for the filing.

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>Physical appearance: Freeze dried powder</td>
</tr>
<tr>
<td>Corrosive:</td>
</tr>
<tr>
<td>Stable:</td>
</tr>
<tr>
<td>Oxidising:</td>
</tr>
<tr>
<td>Hygroscopic:</td>
</tr>
<tr>
<td>Irritant:</td>
</tr>
<tr>
<td>Flammable:</td>
</tr>
<tr>
<td>Handling:</td>
</tr>
<tr>
<td>Other (specify):</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
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

* 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.

Net weight: 0.5 - 1.0 g

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No