Non WHO Reference Material
Bordetella pertussis anti - FHA serum (mouse)
NIBSC code: JNIH-11
Instructions for use
Version 7.0, Dated 09/04/2013

This material is not for in vitro diagnostic use.

1. INTENDED USE
This material is intended to be used for the characterisation of acellular pertussis vaccines from different origins. It was originally held by the Statens Serum Institut (SSI), Copenhagen, Denmark. With effect from 1st July 1997, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK became the custodian and distributor of this material.

Details from the original SSI package insert are incorporated into this Instruction for Use.

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
(See section 7)

4. CONTENTS
Country of origin of biological material: Japan.
Each ampoule contains about 56 mg of dry material with a moisture of about 0.5%. It was freeze dried from a buffer solution containing phosphate buffered saline and glycine.

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
JNIH-11 is a pooled freeze dried preparation of IgG (obtained by ammonium sulphate precipitation) from mice immunized against purified FHA. It was manufactured by the Biken Kanonji Institute in Japan on June 22nd 1987 and replaces an earlier preparation JNIH-8 which was found to be unsuitable. Ampoules have been marked JNIH-11 (Japanese national institute of Health

So far this preparation has not been finally established as an international reference material but it is stated by the manufacturer that, when tested by ELISA, JNIH-11 has a potency of 400 anti-FHA units per ampoule. This unit is not an internationally defined IU.

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.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES
Proposed guidelines and protocols for the quality control of acellular pertussis vaccines.
J.G.Kreeftenberg, RIVM, PO Box 1, NL-3720, Bilthoven, The Netherlands.

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>
<th>Toxicological properties</th>
</tr>
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<tbody>
<tr>
<td><strong>Physical appearance:</strong> Freeze dried powder</td>
<td><strong>Effects of inhalation:</strong> Not established, avoid inhalation</td>
</tr>
<tr>
<td><strong>Stable:</strong> Yes</td>
<td><strong>Effects of ingestion:</strong> Not established, avoid ingestion</td>
</tr>
<tr>
<td><strong>Hygroscopic:</strong> No</td>
<td><strong>Effects of skin absorption:</strong> Not established, avoid contact with skin</td>
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<tr>
<td><strong>Flammable:</strong> No</td>
<td><strong>Suggested First Aid</strong></td>
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<tr>
<td><strong>Handling:</strong> See caution, Section 2</td>
<td>Inhalation: Seek medical advice</td>
</tr>
</tbody>
</table>

Other (specify): **Contains material of mouse origin**
**Ingestion:** Seek medical advice.

**Contact with eyes:** Wash with copious amounts of water. Seek medical advice.

**Contact with skin:** Wash thoroughly with water.

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**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.

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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*: Japan</th>
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* 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>
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<tr>
<th>Net weight: 0.5 - 1.0 g</th>
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<tr>
<th>Toxicity Statement: Non-toxic</th>
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| Veterinary certificate or other statement if applicable. Attached: No |
The preparation

A sterile vial of the Anti-Pertussis FHA Certified Material contains 5 mg of FHA antigen in 1 ml of phosphate buffered saline. The vial is ready for use and can be stored at 2-8°C. Care must be taken when handling the vial to avoid contamination.

2. APPLICABILITY

The antigen is intended for use in the qualification of anti-Pertussis FHA antibody assays. It should be used in accordance with the protocol of the assay being used.

3. STORAGE

The antigen should be stored at 2-8°C. It is stable for at least 1 year when stored under these conditions.

4. REFERENCE MATERIALS

This reference material is designed for use in the calibration of anti-Pertussis FHA antibody assays. It is intended for use in laboratories where FHA antibody assays are performed.

5. ACKNOWLEDGEMENTS

The authors wish to thank the following institutions for their contribution to the development of this reference material:

- The Department of Health, UK
- The National Institutes of Health, USA
- The European Centre for Disease Control, EU

6. REFERENCES
