Non WHO Reference Material

Serum containing JE virus antibodies and negative control serum

NIBSC code: 02/182; 02/184

Instructions for use

(Version 6.0, Dated 12/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

Japanese encephalitis (JE) virus antibody preparation, 02/182, is derived from individuals who have been immunized with a vaccine containing killed JE virus (Biken, Nakayama strain). This material was evaluated as the candidate International Standard for antibodies to JE virus, ie the primary reference preparation. However, the results of the study indicate that the strain of virus used in PRNT50 assays affects the antibody titre obtained ie when Nakayama virus ie the virus homologous to the strain in the vaccine used to immunise the donors of the plasma, is used higher titres are obtained compared to when a heterologous virus was used. This suggests that the candidate standard may in fact be a strain specific serum. The assignment of a unitage to this material, and expression of potencies relative to it, is therefore inappropriate.

This material is therefore made available as a well characterised serum for use in validation studies. A negative control sample, 02/184, is also available to confirm the specificity of assays.

2. CAUTION

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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 these preparations.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the freeze dried residue of 0.5ml human serum.

5. STORAGE

These materials should be stored on receipt 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

DIcarte 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 contents of each ampoule should be reconstituted in 0.5ml distilled water. This material is for use in PRNT50 assays.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. It is the policy of WHO not to assign an expiry date to their international reference materials. The materials remain valid until they are withdrawn or replaced. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES


10. ACKNOWLEDGEMENTS

We are grateful to the World Health Organisation for funding this project.

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/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 Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No Irritant: No</td>
</tr>
<tr>
<td>Flammable: No Handling: See caution, Section 2 Other (specify): Contains material of human origin</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Suggested First Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation: Seek medical advice</td>
</tr>
</tbody>
</table>

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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
### 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 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>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
<tr>
<td>Net weight</td>
<td>0.5g</td>
</tr>
<tr>
<td>Toxicity Statement</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable, Attached</td>
<td>No</td>
</tr>
</tbody>
</table>