Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

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

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 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

Ferguson M, Johnes S, Li L, Heath A, Barrett A: Effect of genomic variation in the challenge virus on the neutralization titres of recipients of inactivated JE vaccines--report of a collaborative study on PRNT50 assays for Japanese encephalitis virus (JE) antibodies. Biologicals 2008, 36(2):111-116.

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/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			
Physical appearance: Freeze dried powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains materila of human originlease complete		
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		

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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

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

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