Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Anti N1 Neuraminidase Serum
NIBSC code: 04/230
Instructions for use
(Version 4.0, Dated 07/02/2014)

1. INTENDED USE

Influenza antiserum reagent 04/230 is prepared in sheep for neuraminidase identity 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.
The antiserum was prepared in a SHEEP (SH441) to NIBRG-17 (H7N1) virus. NIBRG-17, prepared by reverse genetics at NIBSC, is a reassortant between A/Equine/Prague/ 56 (H7N7) and A/New Caledonia/20/99 (H1N1) viruses. One dose of approximately 10 micrograms of virus protein with Freund's complete adjuvant (FCA) was given intramuscularly, a further dose of approximately 2.5 micrograms with Freund's incomplete adjuvant (FIA), was given two weeks later. This was followed by a further two 2.5 microgram doses, with FIA, at weekly intervals.

Five and half weeks after the initial immunization, serum was collected, sodium azide was added (0.05% w/v). The serum was diluted 1:3 with PBS buffer containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes. The mean weight of 14 vials test weighed was 2.07g with a coefficient of variation of 0.49%.

5. STORAGE

+2-8ºC
.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the material
Reagent 04/230 should be used in tests of neuraminidase identity, such as the neuraminidase inhibition (NI) test of Aymard-Henry M, Coleman MT, Dowdle WR, Laver WG, Schild GC and Webster RG. Bull WHO, 1973, 48, 199-202. Although Reagent 04/230 does not have a unitage, in NI tests of influenza A (H1N1) viruses, homologous titres are usually as indicated in the Appendix. For influenza A (H1N1) viruses isolated after 1999, weaker NI titres may be obtained due to antigenic drift.

8. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

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

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated in section 5.

9. REFERENCES

10. ACKNOWLEDGEMENTS

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: Liquid	Corrosive: No
Stable: Yes	Oxidising: No

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

Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains Sheep Serum and Sodium Azide (0.05% w/v)	
Toxicological properties	
Effects of inhalation: No adverse effects have been reported	
Effects of ingestion: No adverse effects have been reported n	
Effects of skin absorption: No adverse effects have been reported	
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: 2g
Toxicity Statement: Non-Toxic
Veterinary certificate or other statement if applicable**.** **Attached:** Yes SH441

NIBSC
Assuring the quality of biological medicines

COPY

Blanche Lane
South Mimms
Potters Bar
Hertfordshire EN6 3QG
United Kingdom

Tel: +44 (0)1707 641000
Fax: +44 (0)1707 646730

enquiries@nibsc.ac.uk
http://www.nibsc.ac.uk

Veterinary Certificate

This is to certify that Sheep no. 4055 [Virology No. SH 441] was used for the production of blood antiserum between 8th September and 18th October 2004.

This sheep was a ewe that was surplus to breeding requirements, in overt good health, and showed no signs of clinical disease.

The ear tag identifying the animal indicated that it was of UK origin.

R M Hull 27 October 2004

R.M. Hull
BVSc, PhD, MRCVS
Named Veterinary Surgeon