Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Anti N1 Neuraminidase Serum SH485
NIBSC code: 08/126
Instructions for use
(Version 3.0, Dated 22/08/2011)

1. INTENDED USE

Influenza antiserum reagent 08/126 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 (SH485) to NIBRG-74 (H7N1) virus. NIBRG-74, prepared by reverse genetics at NIBSC, is a reassortant between A/equine/Prague/1/56 (H7N7) and A/turkey/Turkey/1/05 (H5N1) viruses. One dose of approximately 20 micrograms of virus protein with Freund's complete adjuvant (FCA) was given intramuscularly, a further dose of approximately 10 micrograms with Freund's incomplete adjuvant (FIA), was given two weeks later. This was followed by a further six 10 microgram doses, with FIA, at weekly intervals.

Nine and half weeks after the initial immunization, serum was collected, sodium azide was added (0.05% w/v). The serum was treated using an APHIS approved method for inactivation of FMD virus, see attache certificate. The serum was filled into vials in 1ml volumes. The mean weight of 25 vials test weighed was 1.0308g with a coefficient of variation of 0.6646%.

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 08/126 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 08/126 does not have a unitage, in NI tests titres are usually as indicated in the Appendix.

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 on the label.

9. REFERENCES

Amard-Henry, M., Coleman, M.T., Dowdle, W.R., Laver, W.G., Schild, G.C and Webster, R.G. 1973. Influenza virus neuraminidase inhibition test procedures. Bull. Wld. Htth. Org. 48: 199-202

10. ACKNOWLEDGEMENTS

This reagent was produced on behalf of the FLUSECURE project with funding from the EU.

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
Hygroscopic: No	Irritant: No

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

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: 1g
Toxicity Statement: Non-Toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No Vet Certificate, FMD Inactivation Certificate and Appendix, including storage Information sheet.

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Assuring the quality of biological medicines

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VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have today examined a Sheep with ear tag number: UK 12241 5462 [Virology no SH 485], which has been used in the production of blood antiserum between 6th February 2008 and 9th April 2008. Both the ear tag number and the animals' record show that it is of UK origin.

This animal was a breeding Ewe which became surplus to requirements. In my opinion at the time of clinical examination, the ewe was in good health and showed no clinical signs of infectious disease.

Kath Hardcastle BVetMed MRCVS
Named Veterinary surgeon
Royal Veterinary College
Royal college Street
London
NW1 OTU

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Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep with ear tag no: UK 12241 5462 [Virology no. SH485] has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus. The treatment method used was maintenance of pH5.5 or lower for a minimum of 30 minutes.

Dr Philip Minor
Deputy Director
National Institute for Biological Standards and Control

Appendix

Neuraminidase inhibition titres of 08/126

Antigen	NI Titre
NIBRG-74 (H7N1) [A/eq/Prague/1/56 x A/tk/Tk/1/05]	1837
NIBRG-23 (H5N1) [A/tk/Tk/1/05 x (A/PR/8/34)]	1051
NYMC X175C (H3N2) [A/Uruguay/716/2007 x (A/PR/8/34)]	103
B/Florida/4/2006	87

NB This data is presented in order to provide an indication of the likely titre of this reagent in a *standard enzyme inhibition assay, on the understanding that individual test results will vary.

*Amard-Henry, M., Coleman, M.T., Dowdle, W.R., Laver, W.G., Schild, G.C and Webster, R.G. 1973. Influenza virus neuraminidase inhibition test procedures. Bull. Wld. Htth. Org. 48: 199-202

STORAGE OF REAGENT 08/126

NIBSC has prepared a number of reagents for single radial diffusion assay of influenza subtypes of pandemic potential.

Since it is not known when these reagents may be required, it is desirable that they have an indefinite shelf life and they are stored at NIBSC in colder conditions than reagents prepared for the assay of epidemic strains. Therefore the recommended storage temperature marked on the label for reagent 08/126 is -20^{o}C.

However it is assumed that a customer ordering this reagent, will use it within a short period similar to that for a conventional reagent. Consequently, this reagent is not normally shipped frozen and **the recommended storage temperature is +4^{o}C.**

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