Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza anti A/Solomon Islands/3/2006 (H1N1) (IVR-145) HA Serum (sheep467,468,469,470)
NIBSC code: 07/104
Instructions for use
(Version 4.0, Dated 30/07/2015)

1. INTENDED USE

Influenza antiserum reagent 07/104 is prepared for single radial diffusion assay of A/Solomon Islands/3/2006 antigens using an appropriate NIBSC antigen reagent as described below.

The antiserum reagent was prepared in sheep 467, 468, 469 and 470 to the purified HA of A/Solomon Islands/3/2006 and IVR-145 (a reassortant with HA and NA from A/Solomon Islands/3/2006). The HA antigen was extracted from purified virus by treatment with bromelain and purified by sedimentation on sucrose gradients (Brand, CN and Skehel, JJ, Nature, New Biology, 1972, 238, 145-147.

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 immunization schedule for sheep 467 and 468 was as follows: One dose of approximately 50-100 micrograms of A/Solomon Islands/3/2006 HA with Freund's Complete Adjuvant (FCA) was given intramuscularly, followed two weeks later with a 10 microgram dose of IVR-145 HA including Freund's Incomplete Adjuvant (FIA), three further 10 microgram doses of IVR-145 HA including FIA were given at weekly intervals. Five and a half weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) was added.

The immunization schedule for sheep 469 and 470 was as follows: One dose of approximately 50-100 micrograms of A/Solomon Islands/3/2006 HA with FCA was given intramuscularly, followed two weeks later with a 10 microgram dose including FIA, four further 10 microgram doses including FIA were given at weekly intervals. Seven and a half weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) was added.

The sera were pooled, and diluted 1:5 with PBS buffer containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes.

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

For the assay of antigens containing 20-50 micrograms of HA activity in 1ml, approximately 10µl of the undiluted Reagent should be added to 1ml agarose. It may be necessary to change the antiserum concentrations according to local laboratory conditions.

Antiserum Reagent 07/104 should be used according to the method described by Wood, JM, Schild, GC, Newman, RW and Seagroatt, VA. Journal of Biological Standardisation, 1977, 5, 2

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

N/A

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.

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

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
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains Sheep Serum and Sodium Azide (0.05% w/v)	
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	
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: Not established
Veterinary certificate or other statement if applicable**.** **Attached:** Yes SH467-468-469-470

THE ROYAL VETERINARY COLLEGE
UNIVERSITY OF LONDON

Dr. R Newman
NIBSC
Blanche Lane
South Mimms
Potters Bar
EN6 3QG

COPY

Dear Dr Newman,

I can confirm that I examined the following 4 mule ewes today at Boltons Park Farm
UK241512 5125 (SH467)
UK241512 5126 (SH468)
UK241512 5112 (SH469)
UK241512 5121 (SH470)

I found the following incidental findings during my clinical examination

5121 enlarged left side of udder due to chronic or previous mastitis.
5112 incisors were worn
5125 incisors were worn

In my opinion, at the time of clinical examination, the ewes were all in good clinical condition and were suitable for enrolment on the trial despite these findings.

SIGNED 11 APRIL 2007

John Fishwick MA VetMB DCHP MRCVS
21 February 2007