Medicines & Healthcare products Regulatory Agency



Influenza Reagent Anti-A/Singapore/1/57 (H2N2) HA serum (Sheep 398) NIBSC code: 00/440 Instructions for use (Version 5.0, Dated 26/01/2024)

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1. INTENDED USE

Influenza antiserum reagent 00/440 is prepared in sheep for singleradial-diffusion assay of A/Singapore/1/57 HA antigens. An appropriate NIBSC antigen reagent should be included in each assay.

2. CAUTION

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

Not human or bovine source material

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 SHEEP (SH398) to the purified haemagglutinin (HA) of A/Japan/305/57 (H2N2) x A/Bel/42 reassortant virus (H2N1). 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. One dose of approximately 50µg of HA with Freund's complete adjuvant (FCA) was given intramuscularly, followed two weeks later with a 10µg dose with FCA and two further 10µg doses with FCA at one week intervals.

Five weeks after the initial immunization, serum was collected, diluted 1:5 with phosphate buffered saline containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes. The mean weight of 8 vials test weighted was 2.04g with a coefficient of variation of 0.28%.

5. STORAGE

+2-8°C

Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Crimp Top Vials

7. USE OF MATERIAL

For the assay of antigens containing 20-50µg of HA activity in 1ml, 15µl of the undiluted Reagent should be added to 1ml of agarose. Antigens of lower concentration (5-20µg HA/ml) are assayed by adding 7.5µl of the Reagent to 1ml of agarose. It may be necessary to change the antiserum concentrations according to local laboratory conditions.

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 Antiserum reagent 00/440 should be used according to the method described by Wood JM, Schild GC, Newman RW and Seagroatt VA. Journal of Biological Standardisation, 1977, 5, 237-247.

8. STABILITY

Reference materials are held at NIBSC within assured, temperaturecontrolled storage facilities. Reference Materials should be stored on receipt as indicated on the label, please also see attached storage information sheet.

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

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.

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:		Corrosive:	No	
straw coloured liquid				
Stable:	Yes	Oxidising:	No	
Hygroscopic:	No	Irritant:	No	
Flammable:	No	Handling:See	e caution, Section 2	
Other (specify):	Contains sheep serum and sodium azide			
Toxicological properties				

Effects of inhalation:	Not established, avoid inhalation
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Effects of ingestion:	Not established, avoid ingestion		
Effects of skin	Not established, avoid contact with		
absorption:	skin		
Suggested First Aid			
Inhalation:	Seek medical advice		
Ingestion:	Seek medical advice		
Contact with	Wash with copious amounts of water. Seek		
eyes:	medical advice		
Contact with skin:	Wash thoroughly with water.		
Action on Spillage and Method of Disposal			
wetted with an appro appropriate disinfect	should be taken up with absorbent material opriate disinfectant. Rinse area with an tant 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 freezedrying.

Net weight: 2g

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable. Attached: Yes SH398 and Storage Information sheet.



STORAGE OF REAGENT 00/440

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 00/440 is -20°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 <u>the recommended storage temperature is +4°C.</u>





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Veterinary Certificate

This is to certify that sheep number R051 (SH398) was used for the production of blood antiserum between August and September 1999 to prepare reagent 00/440.

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

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R.M. Woollon Bvet Med. MRCVS Named Veterinary Surgeon



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