Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza antiserum A/mallard/Netherlands/12/2000
NIBSC code: 07/278
Instructions for use
(Version 4.0, Dated 16/05/2019)

1. INTENDED USE

Influenza antiserum reagent 07/278 is prepared in sheep for single radial diffusion assay of A/mallard/1Netherlands/12/2000 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.

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 sheep SH474 and SH475 to the purified HA of HGR, NIBRG-60 (derived from A/mallard/Netherlands/12/2000). The HA antigen was extracted from inactivated and 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). The immunisation schedule for SH474 and SH475 were as follows: One dose of approximately 50µg of HA with Freund's complete adjuvant was given intramuscularly, followed two weeks later with a 10µg dose in the presence of Freund's incomplete adjuvant (FIA), three further 10µg doses including FIA were given at weekly intervals. Six weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) was added.

Serum SH474 and SH475 were treated by maintenance of pH5.49, or lower for 40 minutes followed by restoration of the original pH. They were pooled and diluted with phosphate buffered saline 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 20-50µg of HA activity in 1ml, 20µl of the undiluted Reagent should be added to 1ml of agarose. Antigens of lower concentration (5-20µg HA/ml) are assayed by adding 10µl of the Reagent to 1ml of agarose. It may be necessary to change the antiserum concentrations according to local laboratory conditions.

Antiserum reagent 07/278 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, temperature-controlled 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

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

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

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

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 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 SH474 SH475 plus FMD Inactivation Certificate and Storage Information Sheet.

National Institute for Biological Standards and Control,
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STORAGE OF REAGENT 07/278

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 07/278 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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NIBSC
Assuring the quality of biological medicines

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

Tel:+44 (0)1707 641000
Fax:+44 (0)1707 641050
Email:enquiries@nibsc.ac.uk
Web:http://www.nibsc.ac.uk

Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected and pooled from Sheep no. UK 281 038 5374 and Sheep no. UK 281 038 5413 [Virology no.SH474 and SH475 respectively] 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 40 minutes.

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

NIBSC
Assuring the quality of biological medicines

Blanch Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG
Tel: +44 (0) 1707 641000
Fax: +44 (0)1707 646730
Email: enquiries@nibsc.ac.uk
http://www.nibsc.ac.uk

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have today examined a Sheep with ear tag number: UK 281 038 5374 [Virology no SH 474, which has been used in the production of blood antiserum between 31 August 2007 and 10 October 2007. 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.

John Fishwick MRCVS
Veterinary Surgeon
Royal Veterinary College
Hawkshead Lane
North Mymms
Hatfield
AL9 7TA

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Blanch Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG
Tel: +44 (0) 1707 641000
Fax: +44 (0)1707 646730
Email: enquiries@nibsc.ac.uk
http://www.nibsc.ac.uk

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