



Influenza Reagent
Influenza antiserum A/Japan/305/57 (H2)
NIBSC code: 08/356
Instructions for use
(Version 2.0, Dated 22/08/2011)

1. INTENDED USE

Influenza antiserum reagent 08/356 is prepared in sheep for single radial diffusion assay of A/Japan/305/57-like antigens. An appropriate NIBSC 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 reagent was prepared in sheep SH398 to the purified HA of A/Japn/305/57. 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.

The immunisation schedule for sheep SH398 was as follows: One dose of approximately 25-50 micrograms of A/Japan/305/57 HA with Freund's Complete Adjuvant was given intramuscularly, followed two weeks later with a 25-50 microgram dose of A/Japan/305/57 HA with Freund's Incomplete Adjuvant (FIA), two further 10-20 microgram doses of A/Japan/305/57 HA with FIA were given at weekly intervals. five weeks after the initial immunisation, serum was collected and sodium azide (0.05% w/v) was added.

The serum was treated by maintenance of pH5.49 for 40 minutes followed by restoration of the original pH and then diluted 1:7 with phosphate buffered saline containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes.

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

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

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For the assay of antigens containing 20-50 micrograms of HA activity in 1ml, approximately 20µl 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 08/356 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: Yes | 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 |



| 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

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|---|
| 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 SH398 Plus FMD Inactivation Certificate and Storage Information sheet. |



STORAGE OF REAGENT 08/356

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 08/356 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 **the recommended storage temperature is $+4^{\circ}\text{C}$.**



Assuring the quality of biological medicines

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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.

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

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



A World Health Organization
International Laboratory
for Biological Standards

National Institute for Biological Standards and Control



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Accredited laboratories
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UK Official Medicines Control Laboratory



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Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep no. R051 [Virology no. SH398] has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus. The treatment method used was maintenance of pH 5.5 or lower for a minimum of 40 minutes.

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



National Institute for Biological Standards and Control

