Medicines & Healthcare products Regulatory Agency



Influenza Reagent Influenza anti A/Panama/2007/99 HA Serum NIBSC code: 02/338 Instructions for use (Version 3.0, Dated 03/04/2008)

1. INTENDED USE

Influenza reagent 02/238 is prepared in sheep for the single radial diffusion assay of A/Panama/2007/99 antigens.

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 SH418 to the purified HA of A/Panama/2007/99 virus. 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 50 micrograms of HA with Freund's complete adjuvant (FCA) was given intramuscularly, followed two weeks later with a 10 microgram dose including Freund's Incomplete Adjuvant (FIA) and one further 10 microgram dose one week later.

Four weeks after the initial immunization, the serum was collected, diluted 1:4 with PBS buffer containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes. The mean weight of 41 vials test weighed was 2.04g with a coefficient of variation of 0.71%.

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

No attempt should be made to weigh out any portion of the material

For the assay of antigens containing 20-50 micrograms of HA activity in 1ml, approximately 14µl of undiluted Reagent should be added to 1ml agarose. Antigens of lower concentration (5-20 micrograms HA/ml) are assayed by adding 7µl of the Reagent to 1ml agarose. It may be necessary to change these antiserum concentrations according to local laboratory conditions.

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w/v)

Physical	Corrosive:	No
appearance: liquid		
Stable:	Oxidising:	No
Yes		
Hygroscopic:	Irritant:	No
No		
Flammable:	Handling:	See caution, Section 2
No		
Other (specify): C	ontains sheep serum	and sodium azide (0.05%)

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

Antiserum Reagent 02/338 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.

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

9. REFERENCES

None

10. ACKNOWLEDGEMENTS None

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

UK Official Medicines Control Laboratory



Suggested First Aid		
Inhalation:	Seek medical advice	
Ingestion:	Seek medical advice	
Contact with eyes: medical advice	Wash with copious amounts of water. Seek	
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: Non toxic

Veterinary certificate or other statement if applicable. Attached: Yes SH418

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Veterinary Certificate

This is to certify that sheep number 3112 was used for the production of blood antiserum between March and April 2002 to prepare reagent SH418.

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

R.M. Woollon B. Vet. Med MRCVS Named Veterinary Surgeon

9.7.07

Sheep serum SH418 was used to prepare NIBSC Antiserum reagent 02/338

Una Dunleavy Study Director, Influenza



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