



Influenza Reagent Influenza Anti-A/Perth/16/09-like HA serum NIBSC code: 10/182 Instructions for use (Version 1.0, Dated 17/09/2010)

1. INTENDED USE

Influenza antiserum reagent 10/182 is prepared for single radial diffusion assay of A/Perth/16/09-like antigens using an appropriate NIBSC antigen reagent.

The antiserum reagent was prepared in sheep 526, 527 and 528 to the purified HA of A/Victoria/210/09 (NYMCX-187). The HA antigens were 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.

CAUTION 2.

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 all sheep was as follows: One dose of approximately 50µg of A/Victoria/210/09 (NYMCX-187) HA with Freund's Complete Adjuvant (FCA) was given intramuscularly, followed two weeks later with a 10 microgram dose of including Freund's Incomplete Adjuvant (FIA). Four weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) added. The serum was then treated by an APHIS approved method for the inactivation of FMDV.

The seraum was then diluted 1:4 with PBS buffer 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

For the assay of antigens containing 20-50 micrograms of HA activity in 1ml, approximately 12µl of the undiluted reagent should be added to 1ml agarose. It may be necessary to change the antiserum concentrations according to local laboratory conditions.

National Institute for Biological Standards and Control,

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Antiserum Reagent 10/182 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, temperaturecontrolled 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

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			
Physical appearance: Liquid	Corrosive:	No	
Stable: Yes	Oxidising:	No	

Medicines & Healthcare products Regulatory Agency



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				
material wetted with appropriate disinfec	an appropriate distant followed by wa	e taken up with absorbent sinfectant. Rinse area with an ater.		

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 SH526 SH526a SH527 SH527a SH528 SH528a			



Royal Veterinary College University of London Lucy Whitfield Named Veterinary Surgeon Royal Veterinary College Royal College Street LONDON NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have today examined a sheep with ear tag number: UK 265 852 202 [Virology no. SH526], which has been used in the production of blood antiserum between 29th July 2010 and 24th August 2010. Both the ear tag number and the animal's 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.

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Lucy Whitfield MA VetMB DLAS MRCVS Named Veterinary Surgeon

> Lucy Whitfield MA VetMB DLAS MRCVS Phone/Fax 020 7468 5333 Mobile: 07778 332464 Email: <lwhitfield@rvc.ac.uk>







Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep with ear tag number: UK 265 852 202 (Virology no.SH526) has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus (FMDV). The treatment method used was maintenance of pH5.5 or lower for a minimum of 30 minutes.

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

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Royal Veterinary College University of London Lucy Whitfield Named Veterinary Surgeon Royal Veterinary College Royal College Street LONDON NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have today examined a Sheep with ear tag number: UK 265 852 292 [Virology no. SH527], which has been used in the production of blood antiserum between 29th July 2010 and 24th August 2010. 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.

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Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep with ear tag number: UK 265 852 292 (Virology no.SH527) has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus (FMDV). The treatment method used was maintenance of pH5.5 or lower for a minimum of 30 minutes.

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

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VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have today examined a sheep with ear tag number: UK 265 852 271 [Virology no. SH528], which has been used in the production of blood antiserum between 29th July 2010 and 24th August 2010. Both the ear tag number and the animal's 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. Incidental findings were a scant muco-purulent discharge from the left nostril and worn incisors.

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Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep with ear tag number: UK 265 852 271 (Virology no.SH528) has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus (FMDV). The treatment method used was maintenance of pH5.5 or lower for a minimum of 30 minutes.

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

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