Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Anti-A/Darwin/9/2021-like HA serum (H3N2)
NIBSC code: 22/226
Instructions for use
(Version 2.0, Dated 29/08/2025)

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1. INTENDED USE

Influenza antiserum reagent 22/226 is prepared for single radial diffusion assay of A/Darwin/9/2021-like antigens using an appropriate NIBSC antigen reagent.

The antiserum reagent was prepared in sheep 808, 809, 810 and 811 using the purified HA of a A/Darwin/9/2021-like virus. 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)

2. CAUTION

The material is not of human or bovine origin. This preparation is not for administration to humans or animals

3. UNITAGE

No unitage is assigned to this material

4. CONTENTS

Country of origin of biological material: United Kingdom.
The immunization schedule for sheep 808, 809, 810 and 811 was as follows: one dose of approximately 100 µg of A/Darwin/9/2021 (IVR-228) virus HA with Freund's Complete Adjuvant (FCA) was given intramuscularly, followed two weeks later with a 50 microgram dose including Freund's Incomplete Adjuvant (FIA). Two further 50 microgram doses of A/Darwin/9/2021 (IVR-228) HA including FIA were given after a week. Five weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) added.
For the inactivation of FMDV the antiserum was treated by maintenance of pH 5.5 (or lower) for at least 30 minutes followed by restoration of the original pH.
The antisera obtained from sheep 808, 809, 810 and 811 were pooled, diluted 1:6 with PBS buffer containing sodium azide (0.05% w/v), and filled into vials in 2ml volumes

5. STORAGE

The recommended storage temperature is +2-8°C. However, if it is intended to store the reagent for long periods (i.e. > 2 years) it may be stored at -20°C. The antiserum can be frozen and thawed without any adverse impact on use in the SRD assay.
Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

For the assay of antigens containing 20-50 micrograms of HA activity in 1ml, approximately 20-30 µl of the undiluted reagent should be added to 1ml agarose. It may be necessary to change the antiserum concentrations depending on the A/Darwin/9/2021-like antigen standard used or according to local laboratory conditions.
Antiserum Reagent 22/226 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

Reference materials are held at NIBSC within assured, temperature-controlled 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.

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.

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

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 (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
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 SH808 SH809 SH810 SH811

Royal Veterinary College
University of London

Alex McSloy
Named Veterinary Surgeon
Royal Veterinary College
Royal College Street
LONDON
NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 014795405718 [Virology no. SI1808], which has been used in the production of blood antiserum between 19th October 2022 and 23rd November 2022. 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.

Alex McSloy MA VetMB DipACVIM PhD MRCVS
Named Veterinary Surgeon

Date signed: 22 Nov 2022

Alex McSloy
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Tel: +44 (0)1707 666333, E-mail: amcsloy@rvc.ac.uk

Royal Veterinary College
University of London

Alex McSloy
Named Veterinary Surgeon
Royal Veterinary College
Royal College Street
LONDON
NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 014795405509 [Virology no. SI1809], which has been used in the production of blood antiserum between 19th October 2022 and 23rd November 2022. 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.

Alex McSloy MA VetMB DipACVIM PhD MRCVS
Named Veterinary Surgeon

Date signed: 22 Nov 22

Alex McSloy
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Tel: +44 (0)1707 666333, E-mail: amcsloy@rvc.ac.uk

Royal Veterinary College
University of London

Alex McSloy
Named Veterinary Surgeon
Royal Veterinary College
Royal College Street
LONDON
NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 014795405597 [Virology no. SI1810], which has been used in the production of blood antiserum between 19th October 2022 and 23rd November 2022. 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.

Alex McSloy MA VetMB DipACVIM PhD MRCVS
Named Veterinary Surgeon

Date signed: 22 Nov 22

Alex McSloy
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Tel: +44 (0)1707 666333, E-mail: amcsloy@rvc.ac.uk

Royal Veterinary College
University of London

Alex McSloy
Named Veterinary Surgeon
Royal Veterinary College
Royal College Street
LONDON
NW1 0TU

VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 014795408222 [Virology no. SI1811], which has been used in the production of blood antiserum between 19th October 2022 and 23rd November 2022. 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.

Alex McSloy MA VetMB DipACVIM PhD MRCVS
Named Veterinary Surgeon

Date signed: 22 Nov 22

Alex McSloy
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Tel: +44 (0)1707 666333, E-mail: amcsloy@rvc.ac.uk