Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Anti N2 Neuraminidase Serum (A/South Australia/34/2019)
NIBSC code: 19/320
Instructions for use
(Version 1.0, Dated 15/10/2020)

1. INTENDED USE

Influenza antiserum reagent 19/320 is prepared in sheep for neuraminidase identity tests.

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 SH 735 and SH 736, immunised with NIBRG-434 (H7N2) virus. NIBRG-434 is a reassortant developed at NIBSC with the HA gene from A/equine/Prague/1/1956 (H7N7), the NA gene from A/South Australia/34/2019 (H3N2) and the six internal genes from A/PR/8/34 (H1N1). The cleavage site motif in the HA gene has been modified to a monobasic cleavage site. One dose of approximately 600 micrograms of inactivated purified whole virus with Freund's complete adjuvant (FCA) was given intramuscularly. A further dose of approximately 35 micrograms, with Freund's incomplete adjuvant (FIA), was given after two weeks. This was followed by six further doses of 35 micrograms with FIA.
Nine weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) was added. The serum was then treated by an APHIS approved method for the inactivation of FMDV, then filled into vials in 1ml volumes.

5. STORAGE

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.
+2-8ºC

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

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

Reagent 19/320 should be used in tests of neuraminidase identity, such as the neuraminidase inhibition (NI) test of Aymard-Henry M, Coleman MT, Dowdle WR, Laver WG, Schild GC and Webster RG. Bull WHO, 1973, 48, 199-202.

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, 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.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
Hygroscopic: No	Irritant:	No
Flammable: No	Handling:	See caution, Section 2

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

Other (specify): Contains Sheep Serum and Sodium Azide (0.05% w/v)
Toxicological properties
Effects of inhalation: Avoid inhalation
Effects of ingestion: Avoid ingestion
Effects of skin absorption: 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: 1g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** Yes SH735 SH736

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

RVC Royal Veterinary College
University of London

Chris Handley DVM MRCVS
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 0101675 05585 [Virology no. SH735], which has been used in the production of blood antiserum between 18th March 2020 and 20th May 2020. 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.

Chris Handley DVM MRCVS
Named Veterinary Surgeon

Date signed: 20/05/2020

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VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 0117966 02375 [Virology no. SH736], which has been used in the production of blood antiserum between 18th March 2020 and 20th May 2020. 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.

Chris Handley DVM MRCVS
Named Veterinary Surgeon

Date signed: 20/05/2020

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