

# Influenza Reagent Influenza anti-B/Colorado/06/2017-like HA serum NIBSC code: 18/170 Instructions for use (Version 1.0, Dated 18/10/2018)

#### 1. INTENDED USE

Influenza antiserum reagent 18/170 is prepared for single radial diffusion assay of B/Colorado/06/2017-like antigens (B/Victoria/2/87 lineage) using an appropriate NIBSC antigen reagent.

The antiserum reagent was prepared in sheep 686 and 687 using the purified HA of a B/Colorado/06/2017-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.

Minor cross-reactivity for B/Phuket/3073/2013 - like strains has been detected.

#### 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 immunization schedule for sheep 686 and 68 $\check{7}$  was as follows: one dose of approximately 50  $\mu g$  of B/Alabama/02/2017 virus 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 further 10 microgram doses of B/Alabama/02/2017 HA including FIA were given after a week. Seven weeks after the initial immunization, serum was collected and sodium azide (0.05% w/v) added.

The antiserum was then treated by an APHIS approved method for the inactivation of FMDV.

The antisera obtained from sheep 686 and 687 were pooled, diluted 1:7.5, with PBS buffer containing sodium azide (0.05% w/v), and filled into vials in 2ml volumes.

## 5. STORAGE

+2-8°C

However, if it is intended to store the reagent for long periods i.e. >2 years, they may be stored at -20°C. The antiserum can be frozen and thawed without any adverse impact on its use in the SRD assay.

#### 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 ul of the undiluted reagent should be added to 1ml agarose. It may be necessary to change the antiserum concentrations depending on the B/Colorado/06/2017-like antigen standard used or according to local laboratory conditions.

Antiserum Reagent 18/170 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, 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

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





Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

## 15. LIABILITY AND LOSS

biological waste.

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.

Absorbent materials used to treat spillage should be treated as

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 SH686 SH687

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# VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 0101564 01334 [Virology no. SH686], which has been used in the production of blood antiserum between 15<sup>th</sup> August 2018 and 3<sup>rd</sup> October 2018. 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.

Olga Woolmer, DVM, MRCVS Named Veterinary Surgeon

O. Weelee.

Date signed: Or October 2018

> Olga Woolmer, DVM, MRCVS Named Veterinary Surgeons (NVS) Group The Royal Veterinary College, Royal College Street, London NW1 0TU Mobile: 07809 199998, E-mail: owoolmer@rvc.ac.uk





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# VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 0100285 02878 [Virology no. SH687], which has been used in the production of blood antiserum between 15<sup>th</sup> August 2018 and 3<sup>rd</sup> October 2018. 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.

Olga Woolmer, DVM, MRCVS Named Veterinary Surgeon

01 October 2018

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Date signed:

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