Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza anti A/Panama/2007/99 (H3N2) HA serum
NIBSC code: 01/452
Instructions for use
(Version 3.0, Dated 30/05/2014)

1. INTENDED USE

influenza antiserum reagent 01/452 is prepared in sheep for the single radial diffusion assay of A/Panama/2007/99 antigens.

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 a SHEEP (SH410/411) 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, C N 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 into each of two sheep, followed two weeks later with a 10 microgram dose and two further doses at weekly intervals.
Eight weeks after the initial immunization, each serum was collected , sodium azide (0.05% w/v) was added and the sera were exposed tp pH5 for a two hour period in order to comply with EC foot and mouth disease decision. The sera were pooled, diluted 1:3 with PBS buffer containing sodium azide (0.05% w/v) The serand filled into vials in 2ml volumes. The mean weight of 28 vials test weighed was 2.015g with a coefficient of variation of 0.41%
Reagent 01/452 has been exposed th pH5 for 2 hours and has subsequently been tested and found negative for foot and mouth disease virus (FMDV) activity by rt PCR.. Both sheep used to produce 01/452 were in good health, with no symptoms of FMDV
Serum reagent 01/452 thus complies with EC Descision of 08 March 2001 (2001/190/EC) concerning protection measures with regard to FMDV in the UK.

5. STORAGE

+2-8ºC

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 8µl of undiluted reagent should be added to 1ml agarose. Antigens of lower concentration (5-20 micrograms HA/ml) are assayed by adding 4µl of the reagent to 1ml agarose. It may be necessary to change these antiserum concentrations according to local laboratory conditions. The clarity of the SRD zones may be improved ny washing the gels with PBS before pressing and staining

Antiserum Reagent 01/452 should be used according to the method described by Wood, JM, Schild, GC, Newman, RW and Seagroatt, VA Jornal of Biological Standarisation, 1977, 5, 237-247.

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.

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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: 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: 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: 2g
Toxicity Statement: Non toxic
Veterinary certificate or other statement if applicable**.** **Attached:** Yes SH410-411

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Veterinary Certificate

Reagent 01/452

This is to certify that sheep numbers 2179 (SH410) and 2188 (SH411) were used for the production of blood antiserum between April and June 2001 to prepare reagent 01/452.

The sheep were ewes on the Royal Veterinary College Boltons Park Farm, Brookmans Park, Hertfordshire, UK that were surplus to breeding requirements, in good health and showed no signs of clinical disease.

From February to April 2001, there have been no cases of foot and mouth disease within a 20 mile radius of the farm*.

Reagent 01/452 has been inactivated by exposure to pH5 for 2 hours and has been tested negative for foot and mouth disease virus by the Central Public Health Laboratory, Colindale, UK. The reagent thus complies with the European Commission Decision of 8 March 2001 (2001/190/EC), concerning protection measures with regard to foot and mouth disease in the UK.

Reagent 01/452 is only for laboratory use as an *in vitro* diagnostic reagent.

7.6.01

R.M.Woollon
Bvet Med MRCVS
Named Veterinary Surgeon

4/6/01

J.M.Wood PhD
Principal Scientist
Division of Virology

* Information from http://www.maff.gov.uk