Influenza Reagent
Influenza Anti A/Anhui/1/2013 (H7) HA serum
NIBSC code: 15/248
Instructions for use
(Version 1.0, Dated 27/10/2016)

1. INTENDED USE
Influenza antiserum reagent 15/248 is prepared in sheep for single radial diffusion assay of A/Anhui/1/2013 antigens. An appropriate NIBSC reagent should be included in each assay.

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 reagent was prepared in sheep SH644 and 645 to the purified recombinant HA of A/Anhui/1/2013 virus. The HA antigen is a full-length glycosylated recombinant protein, produced by Protein Sciences Corporation in insect cells using the baculovirus expression vector system and purified to >90% purity and subject to QC testing.

The immunisation schedules for sheep SH644 and SH645 were as follows: One dose of approximately 50 micrograms of HA with Freund’s Complete Adjuvant was given intramuscularly, followed two weeks later with an approximate 10 microgram dose of HA with Freund’s Incomplete Adjuvant (FIA). For SH644, two further approximate 10 microgram doses of HA with FIA were given at weekly intervals. Five weeks after the initial immunisation, serum was collected and sodium azide (0.05% w/v) was added. For SH645, four further approximate 10 microgram doses of HA with FIA were given at weekly intervals. Seven weeks after the initial immunisation, serum was collected and sodium azide (0.05%) was added.

The sera were treated by maintenance of pH5.49 (or lower) for 30 minutes followed by restoration of the original pH. The sera were pooled and diluted 1:2 with phosphate buffered saline containing sodium azide (0.05% w/v) and filled into vials in 2ml volumes.

5. STORAGE
+2-8°C Please see the appendix sheet attached to this IFU.
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 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 20µl of the undiluted Reagent should be added to 1ml agarose. It may be necessary to change the antiserum concentrations according to local laboratory conditions.

Antiserum Reagent 15/248 should be used according to the method described by Wood, JM, Schild, GC, Newman, RW and Seagroatt, VA. Journal of Biological Standardisation, 1977, 5, 237-247.

8. STABILITY
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities.

NIBSC follows the policy of WHO with respect to its reference materials.

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 materials 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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: straw coloured liquid</td>
</tr>
<tr>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
</tr>
<tr>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
</tr>
<tr>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Contains sheep serum and sodium azide</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>

N/A
Suggested First Aid

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Contact with eyes</td>
<td>Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td>Contact with skin</td>
<td>Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

Action on Spillage and Method of Disposal

- Spillage of 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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Net weight</th>
<th>2g</th>
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<table>
<thead>
<tr>
<th>Toxicity Statement</th>
<th>Non-toxic</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Veterinary certificate or other statement if applicable.</th>
<th>Attached: Yes Vet certificates. Plus FMD Inactivation Certificates and a Storage Information sheet.</th>
</tr>
</thead>
</table>
STORAGE OF REAGENT 15/248

NIBSC has prepared a number of reagents for single radial diffusion assay of influenza subtypes of pandemic potential.

Since it is not known when these reagents may be required, it is desirable that they have an indefinite shelf life and they are stored at NIBSC in colder conditions than reagents prepared for the assay of epidemic strains. Therefore the recommended storage temperature marked on the label for reagent 15/248 is -20°C.

However it is assumed that a customer ordering this reagent, will use it within a short period similar to that for a conventional reagent. Consequently, this reagent is not normally shipped frozen and the recommended storage temperature is +4°C.
Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep no. 0263 731 00616 [Virology nos.SH644] has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus. The treatment method used was maintenance of pH5.5 or lower for a minimum of 30 minutes.

Dr Philip Minor
Deputy Director
National Institute for Biological Standards and Control
Foot and Mouth Disease Virus Inactivation Certificate

This is to certify that serum collected from Sheep no. 0263 731 00676 [Virology nos.SH645] has been treated by an APHIS approved method for inactivation of Foot and Mouth Disease Virus. The treatment method used was maintenance of pH 5.5 or lower for a minimum of 30 minutes.

Dr Philip Minor
Deputy Director
National Institute for Biological Standards and Control
VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 0263 731 00616 [Virology no. SH644], which has been used in the production of blood antiserum between 30th September 2015 and 3rd November 2015. 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

Arturo Fernandez DVM MRCVS
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Mobile: 07733 103881, E-mail: ar Fernandez@rvc.ac.uk
VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 0263 731 00676 [Virology no. SH1645], which has been used in the production of blood antiserum between 30th September 2015 and 18th November 2015. 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

Arturo Fernandez DVM MRCVS
Named Veterinary Surgeons (NVS) Group
The Royal Veterinary College, Royal College Street, London NW1 0TU
Mobile: 07733 103881, E-mail: a Fernandez@rvc.ac.uk