Influenza Reagent
Influenza Anti-B Neuraminidase Serum (B/Phuket/3073/2013)
NIBSC code: 21/322
Instructions for use
(Version 2.0, Dated 25/01/2022)

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1. INTENDED USE
Influenza antiserum reagent 21/322 is prepared in sheep for neuraminidase identity tests.

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

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 770, immunised with B/Phuket/3073/2013 recombinant NA. One dose of approximately 50 micrograms of recombinant NA with Freund’s complete adjuvant (FCA) was given intramuscularly. A further dose of approximately 10 micrograms, with Freund’s incomplete adjuvant (FIA), was given two weeks later. This was followed by four further doses of 10 micrograms with FIA and two further doses of 30 micrograms with FIA.

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 the 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
No attempt should be made to weigh out any portion of the material. Reagent 21/322 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
NIBSC follows the policy of WHO with respect to its reference materials. 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 aliquotted, users should determine the stability of the material according to their own method of preparation, storage and use.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

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/jcitlem/
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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Liquid</td>
<td></td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>No</td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
</tr>
<tr>
<td>Other (specify):</td>
<td></td>
</tr>
<tr>
<td>Contains Sheep Serum and Sodium Azide (0.05% w/v)</td>
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</tbody>
</table>

NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

Further information can be obtained as follows;
http://www.nibsc.org/products/ordering.aspx
http://www.nibsc.org/standardisation/international_standards.aspx
http://www.who.int/biologicals/en/
http://www.bipm.org/en/committees/jc/jcitlem/
http://www.nibsc.org/terms_and_conditions.aspx

None

None

None

None

None

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

Page 1 of 3
Toxicological properties

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

**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 SH770 |
VETERINARY CERTIFICATE OF ANIMAL HEALTH

This is to certify that I have examined a Sheep with ear tag number: UK 056403030771 [Virology no. SH770], which has been used in the production of blood antiserum between 12th August 2021 and 27th October 2021. 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

Date signed: 26 OCT 2021

Alex McSloy
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