7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the material.
Reconstitute the total contents of one ampoule of Reagent with 1 ml of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solution of the freeze-dried material. For the assay of virus antigens containing 20-50 micrograms of HA activity in 1 ml, 12 µl of the reagent solution should be added to 1 ml of molten agarose. Antigens of lower concentration (5-20 micrograms HA/ml) are assayed by adding 6 µl of the reagent solution to 1 ml agarose.

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 They remain valid with the assigned potency and status until withdrawn or amended.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.biopm.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

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Influenza Reagent
Influenza anti-A/H1N1/1/83 (X83) HA Serum
NIBSC code: 84/640
Instructions for use
(Version 4.0, Dated 26/03/2008)

1. INTENDED USE
Influenza antiserum reagent 84/640 is prepared in sheep (SH55) for the single radial diffusion assay of A/H1N1/1/83 (X83) 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.

This antiserum was prepared in a sheep (SH55) to the purified HA of A/H1N1/1/83 (X83) virus. The HA antigen was extracted from purified virus by treatment with bromelain and purified by sedimentation on sucrose gradients (Brand, C N & Skehel, J J Nature, New Biology, 1972 238, 145-147).

One dose of approximately 100 micrograms of HA with Freund’s complete adjuvant (FCA) was given intramuscularly, followed 3 weeks later by 3 further doses of 50 micrograms of HA with FCA at 1 week intervals.

Six weeks after the initial immunization, serum was collected, diluted 1:15 with phosphate-buffered saline and processed for freeze-drying in 1ml volumes as described by Campbell P J Journal of Biological Standardization, 1974, 2 249-267.

5. STORAGE

-20°C

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

6. DIRECTIONS FOR OPENING

Take care to avoid aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

A
diagram below. Surround the ampoule with cloth or rubber gloves and avoid touching the ampoule und at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement.

Tap the ampoule gently to collect the material at the bottom (labelled 'B'). The ampoule will snap open.

Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.

Side view of ampoule opening device containing an ampoule positioned ready to open. ‘A’ is the score mark and ‘B’ the point of applied pressure.

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National Institute for Biological Standards and Control, Potters Bar, Hertfordshire, EN6 3QG, T +44 (0)1707 841000, 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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: White powder</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 (0.05% w/v)</td>
</tr>
</tbody>
</table>

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: No