1. INTENDED USE
This material has been prepared from serum of convalescent human cases of pandemic H1N1 and human recipients of A/California/7/2009 (H1N1) (NYMC X179A) vaccine. This is the first International Standard for antibody to influenza H1N1pdm virus. This material will serve as the primary biological standard for antibodies to A/California/7/2009 like virus. Its suitability for this purpose has been assessed in an International Collaborative Study.

2. CAUTION
This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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
This material has been assigned a unitage of 1300 International Units (IU) per ampoule ie. 2600 IU/ml when reconstituted as directed with 0.5ml distilled water.

Uncertainty: the assigned unitage does not carry an uncertainty associated with its calibration. The uncertainty may therefore be considered to be the variance of the ampoule content and was determined to be +/-1.034%.

4. CONTENTS
Country of origin of biological material: Serum from the United Kingdom. The serum is negative for Hepatitis B virus antigen, antibody to human immunodeficiency viruses 1 and 2 and hepatitis C nucleic acid.

Each ampoule contains a freeze-dried residue comprising, under an atmosphere of nitrogen:

Human serum from convalescent cases of pandemic H1N1 and recipients of A/California/7/2009 (H1N1) (NYMC X179A) vaccine

5. STORAGE
Store ampoules at -20°C until use

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

6. DIRECTIONS FOR OPENING
DIN ampoules have an ‘easy-open’ coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure that the disposable ampoule safety breaker is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.

Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The contents of each ampoule should be reconstituted in 0.5ml of distilled water. Once reconstituted, diluted or aliquotted, users should determine the stability of the material according to their own method of preparation, storage and use.

8. STABILITY
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

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

9. REFERENCES

10. ACKNOWLEDGEMENTS

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/standardsation/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 appearance: Freeze-dried</th>
<th>Corrosive: No</th>
</tr>
</thead>
</table>

Physical and Chemical properties

Influenza Reagent
WHO International Standard for antibody to influenza H1N1pdm virus
NIBSC code: 09/194
Instructions for use
(Version 4.0, Dated 03/09/2012)
**Stable:** Yes  
**Oxidising:** No  
**Hygroscopic:** No  
**Irritant:** No  
**Flammable:** No  
**Handling:** See caution, Section 2  
**Other (specify):** Contains material of human origin  

**Toxicological properties**

- **Effects of inhalation:** Not established, avoid inhalation  
- **Effects of ingestion:** Not established, avoid ingestion  
- **Effects of skin absorption:** Not established, 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](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>
<tr>
<td><strong>Net weight:</strong></td>
<td>0.5g</td>
</tr>
<tr>
<td><strong>Toxicity Statement:</strong></td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable.</td>
<td>Attached: No</td>
</tr>
</tbody>
</table>