WHO International Standard
International Standard for antibody to influenza H5N1 virus
NIBSC code: 07/150
Instructions for use
(Version 1.0, Dated 23/04/2009)

1. INTENDED USE
This material has been prepared from plasma of human recipients of A/Vietnam/1194/2004 (H5N1) (NIBRG-14) vaccine. This is the first International Standard for antibody to influenza H5N1 virus. This material will serve as the primary biological standard for antibodies to A/Vietnam/2004 H5N1 Clade 1 virus. In the collaborative study in which this material was calibrated in International Units, it was shown that this material is not suitable as a biological standard for antibodies to H5N1 viruses from other genetic clades.

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. UNTAGE
This material has been assigned a unitage of 1000 International Units per ampoule following an International Collaborative Study to evaluate this material.

   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 +/- 0.28%.

4. CONTENTS
Country of origin of biological material: Plasma from P.R. China and Hungary; further processing in the United Kingdom. The plasma 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 plasma from recipients of A/Vietnam/2004 H5N1 Clade 1 virus vaccine.

5. STORAGE
Store ampoules at -20° 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 provided is open. The safety breaker is designed to allow the ampoule to be held at the 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 1ml of distilled water. Once reconstituted, diluted or aliquoted, 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
None available at present.

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/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


<table>
<thead>
<tr>
<th>Physical appearance</th>
<th>Freeze dried</th>
<th>Corrosive:</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable:</td>
<td>Yes</td>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>No</td>
<td>Irritant:</td>
<td>No</td>
</tr>
</tbody>
</table>
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 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

**17. CERTIFICATE OF ANALYSIS**

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bodproduc/publications/TRS932Annex2_Inter_bio_restdstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.