WHO Reference Reagent
Anti-EBOV plasma, human
NIBSC code: 15/220
Instructions for use
(Version 1.0, Dated 03/11/2015)

1. INTENDED USE
The WHO Reference Reagent for anti-EBOV plasma, human (NIBSC code 15/220) has been established by the WHO Expert Committee on Biological Standardisation (ECBS) for use in neutralisation, pseudotype neutralisation and enzyme immunoassays for antibodies against Ebola virus. 15/220 was assessed in a WHO international collaborative study and is also known as EBOV Ab Sample Code 79.

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

The source material has been tested and found negative for HBsAg, anti-HIV, HCV RNA and EBOV 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
WHO Reference Reagent for anti-EBOV plasma, human has an assigned unitage of 1 unit/mL, i.e. 0.1 units per vial.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each vial contains 100 µL of frozen human plasma from a donor recovered from Ebola virus disease. The original material has been tested by two independent diagnostic laboratories and found negative for Ebola virus RNA using validated RT-PCR assays. The material has also been solvent-detergent treated using a method validated at NIBSC for the inactivation of HIV-1 IIIB spiked into plasma. The solvent-detergent treated plasma has been tested for cytotoxicity against cell lines typically used in Ebola virus neutralisation assays. No cytotoxicity was observed for 15/220 against CHO K1, 293TT, Vero and Vero E6 cell lines.

5. STORAGE
Vials should be stored at -20°C or below upon receipt.
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.
Vials have a screw cap. The cap should be removed by turning anti-clockwise. Care should be taken on removal of cap to prevent the contents escaping.

7. USE OF MATERIAL
The product may be used to calibrate secondary reference materials, for example, by determining the equivalent concentration of secondary reference reagent being calibrated, against the reference reagent, in parallel. The secondary reference reagent can then be assigned a concentration in terms of the “units”.

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. No stability studies have been performed on 15/220 to date. NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES
N/A

10. ACKNOWLEDGEMENTS
We gratefully acknowledge the important contributions of the collaborative study participants. We would also like to thank NIBSC Standards Production and Development for distribution of the candidate materials. We also thank David Wood, Michal Neubling and Patricia Fast of the WHO and participants of teleconferences for their support, guidance and advice. Collaborative study source materials were kindly donated by Hua Wu, Jerry Pommer, Eddie Sullivan (SAB Biotherapeutics, Sioux Falls, South Dakota, USA); Teresa Lambe, Sarah Gilbert, Adrian Hill and Katie Ewer (Jenner Institute, University of Oxford, UK); Annie Winkler (Emory University, USA); Scott Koepell (University of Nebraska); Arne Brantsaeter, Richard Olausson, Unni Bergerud (Oslo University Hospital); Sheila MacLennan, Alex Barber (National Health Service Blood and Transplant, Leeds, UK). We also thank colleagues Maria Zambon, Angie Lackenby, Simon Carne, Pamela Saunders, Meera Chand and Kevin Brown at Public Health England, Colindale, UK for PCR testing of plasma samples. We also thank Steven A. Rubin, FDA/CBER, USA for facilitating the sample permits and shipments to laboratories in the USA.
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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
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: Frozen, pale yellow 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:</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Other (specify):</td>
</tr>
</tbody>
</table>

**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. |
| Toxicity Statement: | Non-toxic |
| Net weight: | 0.1g |
| 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/bloodproducts/publications/TRS932Annex2_Inter_bioolefstandardsrev2004.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.