



**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 IIB 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

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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

Physical and Chemical properties		
Physical appearance: Frozen, pale yellow liquid	Corrosive:	No
Stable: Yes	Oxidising:	No
Hygroscopic: No	Irritant:	No



Flammable:	No	Handling: See caution, Section 2
Other (specify):	N/A	
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: 0.1g
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/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.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.