



**WHO International Standard
1st International Standard for Ebola virus (EBOV) antibodies -
Sierra Leone Convalescent Plasma Pool
NIBSC code: 15/262
Instructions for use
(Version 2.0, Dated 07/08/2018)**

1. INTENDED USE

The WHO 1st International Standard for Ebola virus (EBOV) antibodies - Sierra Leone Convalescent Plasma Pool (NIBSC 15/262), is the freeze-dried equivalent of 0.5 mL pooled convalescent plasma obtained from six Sierra Leone patients recovered from Ebola virus disease (EVD). 15/262 was evaluated in a WHO international collaborative study (1). It is intended that 15/262 is used in the standardization of assays for the detection and quantitation of EBOV antibodies.

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. The convalescent plasmas are confirmed PCR-negative for Ebola virus and were solvent detergent-treated prior to their development into the candidate WHO International Standard (2). 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

In October 2017, the WHO Expert Committee for Biological Standardization (ECBS) adopted the Sierra Leone anti-EBOV convalescent plasma pool preparation (NIBSC 15/262) as the WHO 1st International Standard for EBOV antibodies with an assigned potency of 1.5 IU/mL when reconstituted in 0.5 mL sterile distilled water.

4. CONTENTS

Country of origin of biological material: Sierra Leone.
Each ampoule contains the freeze-dried equivalent of 0.5 mL pooled human plasma.

5. STORAGE

15/262 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

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufacturers instructions provided with the ampoule breaker.

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 (labeled) end. Ensure that the disposable ampoule safety breaker provided 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

This material should be reconstituted in 0.5 mL sterile distilled water. Following addition of water, the ampoules may be left at ambient temperature for approximately 30 minutes until dissolved and then mixed thoroughly, avoiding the generation of excessive foam.

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

1) Wilkinson, D.E., et al. WHO collaborative study to assess the suitability of the 1st International Standard and Reference Panel for antibodies to Ebola virus. 2017. WHO Expert Committee for Biological Standardization. WHO/BS/2017.2316

2) Wilkinson, D.E., et al., WHO collaborative study to assess the suitability of an interim standard for antibodies to Ebola virus. 2015. WHO Expert Committee for Biological Standardization. WHO/BS/2015.2280 post-ECBS

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of the collaborative study participants and the Ebola CP Consortium (1). We also thank David Wood and Micha Nuebling of the WHO and participants of teleconferences for their support, guidance and advice. 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 participating in the study in the USA.

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: Freeze dried	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: 0.50g
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_biol_efstandardsrev2004.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.