WHO International Standard
First International Standard for antibodies to Crimean-Congo haemorrhagic fever virus for neutralisation assays
NIBSC code: 24/228_NT
Instructions for use
(Version1.0, Dated 13/07/2026)

1. INTENDED USE

The First WHO International Standard for antibodies to Crimean-Congo haemorrhagic fever (CCHF) virus is the freeze-dried equivalent of 0.25 mL of pooled plasma obtained from five individuals recovered from CCHF. The preparation has been evaluated in a WHO International collaborative study (1). The intended use of the International Standard is for the calibration and harmonisation of serological assays detecting anti-CCHF virus neutralising antibodies. The preparation has been solvent detergent treated to minimise the risk of the presence of enveloped viruses (2).

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

The assigned potency of the WHO International Standard for antibodies to CCHF virus is 25 IU/ampoule for neutralising antibodies. After reconstitution of the lyophilised cake in 0.25 mL of distilled water or other matrix, the final concentration will be 100 IU/mL.

International Units are arbitrary assigned to a WHO International Standard to express the biological activity of the standard, and as such there is no conversion factor between IU and mass (e.g. ng of antibody)

4. CONTENTS

Country of origin of biological material: United Kingdom.
Country of origin of biological material: Turkey. Each ampoule contains the freeze-dried equivalent of 0.25 mL of pooled human plasma.

5. STORAGE

Ampoules should be stored at -20°C or below 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. 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 manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

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

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.

9. REFERENCES

(1) Bentley et al Collaborative Study for the Establishment of the First WHO International Standard for antibodies to Crimean-Congo haemorrhagic fever virus. 2026 WHO Expert Committee on Biological Standardization. WHO/BS/2026.2504 (2) Dichtelmuller, H.O., et al., Robustness of solvent/detergent treatment of plasma derivatives: a data collection from Plasma Protein Therapeutics Association member companies. Transfusion, 2009. 49(9): p. 1931-43

10. ACKNOWLEDGEMENTS

We would like to wholeheartedly thank the anonymous donors of the serum and plasma samples for their consent which has allowed this study to be undertaken. We gratefully acknowledge the important contributions of the collaborative study participants. Collection of the donations from Turkey were sponsored by CCHFVaccine study, European project 732732 in association with 'Serological Vaccine Standard for Emerging Diseases, Innovate file ref. 971613. Collection of the donations from Uganda and Georgia, and the development of the WHO International Standard has been funded by the Coalition for Epidemic Preparedness Innovations (CEPI).

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):			
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: 0.25 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** False

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 https://www.who.int/publications/m/item/annex2-trs932(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.