



WHO International Standard

**First WHO International Standard for Antibodies to Influenza A
Virus Group 1 HA Stem Domain for binding assays
NIBSC code: 23/144
Instructions for use
(Version 1.0, Dated 19/12/2025)**

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1. INTENDED USE

This preparation was established by the WHO in 2025 as the 1st International Standard for antibodies to the Influenza Virus Group 1 Haemagglutinin (HA) Stem Domain. It is intended to be used for the standardization of binding assays to measure antibody levels against Group 1 HA Stem Domain in human sera. The preparation is a freeze-dried pool of human sera.

2. CAUTION

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

This preparation has been processed under clean controlled conditions but cannot be guaranteed sterile. This preparation has been tested and found to be negative for HBsAg, HIV-1, HIV-2, HIV-1Ag, HCV, Syphilis and Zika virus 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 probably will 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

100 International Units (IU) of anti-HA IgG per ampoule.

4. CONTENTS

Country of origin of biological material: United States of America. Each ampoule contains the freeze-dried residue of 0.5 ml human serum. The candidate standard has been prepared from a bulk of pooled human sera. 0.5 ml aliquots of this bulk were filled in DIN ampoules and freeze dried at NIBSC following documented procedures. This fill was 0.5g fill weight with a mean dry weight of 0.044g. The coefficient of variation (CV) was 0.81%.

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

Ampoules should be reconstituted on the day of the assay by adding exactly 0.5 ml of pure sterile distilled water to give 200 IU/mL. Shake gently without the formation of foam to ensure that all contents are reconstituted.

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. It is the policy of WHO not to assign an expiry date to International Standards. They remain valid with the assigned potency and status until withdrawn or amended. Please note that the stability of International Standard when reconstituted has not been specifically determined. Should users wish to store reconstituted material, they should determine the stability of reconstituted material according to their own method of preparation, storage and use.

9. REFERENCES

- (1) Juan Manuel Carreño et al. 2020. Development and Assessment of a Pooled Serum as Candidate Standard to Measure Influenza A Virus Group 1 Hemagglutinin Stalk-Reactive Antibodies. *Vaccines* 8: 666.
- (2) Report for the establishment of the 1st International Standard for Antibodies to the Influenza Virus Group 1 Haemagglutinin Stem Domain. 2025 WHO Expert Committee on Biological Standardization. WHO/BS/2025.2493.

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of the collaborative study participants. We would also like to thank the MHRA Standards Production, Inventory and Dispatch teams for the filling, freeze-drying and distribution of the candidate material.

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):	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.	

biological reference standards

[https://www.who.int/publications/m/item/annex2-trs932\(revised2004\)](https://www.who.int/publications/m/item/annex2-trs932(revised2004)). 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.

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: 0.445g
Toxicity Statement: Toxicity not assessed
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