Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
2nd International Standard for Antiserum to Respiratory Syncytial Virus
NIBSC code: 16/322
Instructions for use
(Version 1.0, Dated 30/10/2025)

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1. INTENDED USE

The 2nd WHO International Standard (IS) for Antiserum to Respiratory Syncytial Virus (RSV) is intended for the calibration and harmonisation of neutralisation assays detecting antibodies against RSV/A and RSV/B in human samples.

The preparation was evaluated alongside the 1st WHO IS (16/284) in two collaborative studies to evaluate neutralisation of RSV/A (1,2) and RSV/B (3,4). A further report to propose the establishment of the 2nd WHO IS (16/322) and confirm long-term stability was presented to the WHO Expert Committee on Biological Standardization in 2025 (5).

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

960 International Units (IU) of anti-RSV/A neutralizing antibody per ampoule.

690 International Units (IU) of anti-RSV/B neutralizing antibody 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 product is prepared from a pool of 6 human serum samples, from healthy adults presumed to have a history of natural infection.

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
The contents of each ampoule should be reconstituted on the day of assay by the addition of 0.5mL of sterile distilled water.
Following addition of the distilled water, the material must be allowed to become fully reconstituted before use. Gentle shaking of the contents, to avoid the formation of foam, may be used.

Once reconstituted, the WHO IS will have a potency of 1920 IU/mL for RSV/A and 1380 IU/mL for RSV/B neutralising antibody.

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. Therefore, it is recommended that the reconstituted material is for single use only. 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. Multiple freeze/thaw cycles should be avoided.

9. REFERENCES

(1) McDonald, J.U., et al., Establishment of the first WHO International Standard for antiserum to Respiratory Syncytial Virus: Report of an international collaborative study. Vaccine, 2018. 36(50): p. 7641-7649. doi: 10.1016/j.vaccine.2018.10.087
(2) McDonald, J.U., et al., Report on the WHO collaborative study to establish the 1st International Standard for antiserum to Respiratory Syncytial Virus. 2017 WHO Expert Committee on Biological Standardization. WHO/BS/2017.2318
(3) McDonald, J.U. et al., Expansion of the 1st WHO international standard for antiserum to respiratory syncytial virus to include neutralisation titres against RSV subtype B: An international collaborative study. Vaccine, 2020. 38(4): p. 800-807. doi: 10.1016/j.vaccine.2019.10.095.
(4) McDonald, J.U. et al., Update on the WHO collaborative study to establish the 1st International Standard for antiserum to Respiratory Syncytial Virus. 2019 WHO Expert Committee on Biological Standardization. WHO/BS/2019.2372
(5) Stickings P., et al., Report for the establishment of the 2nd International Standard for antiserum to Respiratory Syncytial Virus. 2025 WHO Expert Committee on Biological Standardization. WHO/BS/2025.2498

10. ACKNOWLEDGEMENTS

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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, white cake		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: 0.5 g
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 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.