Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
NIBSC Anti-D (Rho) Antibodies, Serum
NIBSC code: 24/224
Instructions for use
(Version 1.0, Dated 21/03/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

The NIBSC Anti-D(Rho) Antibodies Reference Material is intended for use in performance monitoring of assays for plasma or serum anti-D levels. Such assays may be carried out, for example, for monitoring maternal antibody levels during and after pregnancy [1,2]. It is not intended for the measurement of anti-D concentration in immunoglobulin preparations, nor as a blood grouping reagent. It is the user's responsibility to ensure the suitability of their procedures for assay of anti-D. The reagent is not for in vitro diagnostic use.

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 product coded 24/224 has an estimated potency of 11.5 International Units per ampoule based on automated haemagglutination assays (AutoAnalyser). It is important to note that this estimate is not a formally assigned value.

4. CONTENTS

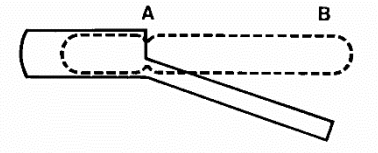
Country of origin of biological material: United Kingdom.
Each ampoule coded 24/224 contains 0.5 ml solution of serum. The Reference Material was prepared from pooled defibrinated human plasma. The freeze-dried preparation was tested and found negative for HBsAg, anti-HIV antibody (WellcozymeR) and HCV RNA by PCR.

5. STORAGE

Unopened ampoules should be stored at -20°C or below.
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The recommended procedure is to dissolve the entire contents of the ampoule in 1.0 mL of 8.5-9.0 g/L sodium chloride containing 5 g/L bovine albumin, then dilute to 50 mL with the same solution (wash the ampoule out well with diluent to recover all the material). This solution may be stored for up to 3 months in aliquots at -40°C. Aliquots should not be re-frozen after use.

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. Stability studies are carried out to ensure the stated stability of this product.

Users are encouraged to provide information on the performance of the reagent in their assay(s), by e-mail (refer to section 12). Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1. HH Gunson, personal communication.
2. Fox, B., Hockley, J. and Studholme, L. (2019), The British Standard for (European Conformity[CE] Marked) Anti-D: Its rarely discussed but important role in quantitating anti-D in patient plasma. Transfusion Med. doi:10.1111/tme.12649

10. ACKNOWLEDGEMENTS

We thank the participants of the collaborative studies.

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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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: Lyophilisate		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.

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: 0.04g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

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UK Official Medicines Control Laboratory