



Working Standard
Working Standard for Anti-Rabies Immunoglobulin
NIBSC code: 19/248
Instructions for use
(Version 1.0, Dated 10/01/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

The Working Standard for Anti-Rabies Immunoglobulin is intended to be used as a secondary standard or positive control in serological assays detecting rabies antibodies. The material has been evaluated in parallel to the Third WHO International Standard for Anti-Rabies Immunoglobulin in a WHO International Collaborative study [1].

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 for 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 Working Standard 19/248 was calibrated to the International Unit (IU) during the collaborative study for the establishment of the Third WHO International Standard for Anti-Rabies Immunoglobulin (NIBSC code: 19/244). The potency for RFFIT and FAVN assays is 18 IU/ampoule with 95% Confidence Limits of 16 - 21. For ELISA methods the potency is 12 IU/ampoule with 95% Confidence Limits of 9 - 16.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried equivalent of 0.5 mL of pooled human serum containing antibodies to rabies virus in response to vaccination.

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 manufacturers 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 in 0.5mL distilled water. Following addition of the distilled water, the material must be allowed to become fully reconstituted before use. End-users have found that it may take > 1 hour with agitation for the material to become fully 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.

The stability of the Working 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.

9. REFERENCES

[1] Wilkinson et al., WHO Collaborative Study to Assess the Candidate 3rd International Standard for Rabies Immunoglobulin. 2022 WHO Expert Committee on Biological Standardization. WHO/BS/2022.2435

10. ACKNOWLEDGEMENTS

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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 Material of human origin (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: 0.5g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No