Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Anti-Dermatophagoides Pteronyssinus Serum, Human
NIBSC code: 77/584
Instructions for use
(Version 6.0, Dated 30/01/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This reference material is comprised of a batch of ampoules coded 77/584. Each ampoule contains the residue after freeze-drying of approximately 0.5ml of pooled undiluted human serum.

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

N/A

4. CONTENTS

Country of origin of biological material: United Kingdom.

Bulk

The bulk material for the NIBSC Research Reagent for D. pteronyssinus serum consisted of a 1100ml pool of frozen pooled human serum provided in 3 bottles, each labelled “alpha-House Dust Mite Serum S402”. The material was collected and supplied by Dr JB Cookson, University of Rhodesia, Salisbury, by arrangement with Dr TG Merrett, Benenden Chest Hospital, Cranbrook, Kent. The sera were collected from a small group of donors whose sera individually showed RAST ratings of 3 for D. farinae. Each donation of blood was taken into citrate phosphate dextrose, coagulation was induced and the resulting sera were pooled, divided into three aliquots, frozen and dispatched to the UK by air freight in solid carbon dioxide.

Distribution into ampoules

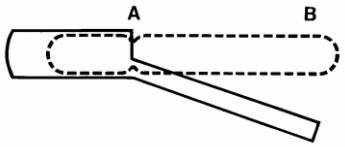
The frozen material in the 3 bottles was thawed at 37°C, the contents pooled and the pooled serum was made homogeneous and filtered through a Millipore membrane ending with a pore size of 0.45µm. The filtered serum, maintained at +4°C, was distributed in 0.5ml aliquots into approximately 2000 ampoules, coded 77/584. The mean weight of liquid contents of 36 checkweight ampoules taken at intervals during the fill was 0.504gm +/- 0.29% (range 0.503-0.506gm). The contents of the ampoules were then freeze-dried and secondary desiccated under the conditions normally used for international biological standards (1). The mean dry weight of ampoule contents was found to be 37.94mg (37.39-38.47mg; n=6) and analysis of the atmosphere within the sealed ampoules gave an oxygen value of 0.06% (range, less than 0.004-0.17%; n=3).

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 total contents of the ampoule should be reconstituted with 0.5ml distilled water and dissolved gently by swirling to avoid froth. No attempt should be made to weigh out any portion of the freeze-dried material. The reconstituted reagent should be used as soon as possible after reconstitution.

Biological Activity

The reagent acts in *in vitro* assays such as radioallergosorbent test (RAST), RAST inhibition, crossed radioimmunoelectrophoresis (CRIE) and immuno-blotting with allergens present in extracts of D. pteronyssinus.

8. STABILITY

It is the policy of WHO not to assign an expiry date to its reference materials. They remain valid with the assigned potency and status until withdrawn or amended. NIBSC follows the policy of WHO with respect to its reference materials.
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. For information specific to a particular biological standard, contact NIBSC.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

Accelerated degradation studies (2) on the contents of unopened ampoules of NIBSC Reagent 77/584 have shown no significant loss of potency as measured by RAST after storage of unopened ampoules for 20 months at temperatures of +20°C and below. Freeze-dried serum stored in unopened ampoules at -20°C has been shown to be extremely stable over a number of years.
Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

9. REFERENCES

1. Campbell, P.J., International Biological Standards and Reference Preparations. II. Procedures used for the production of biological standards and reference preparations. J. Biol. Stand. 2: 259-267 (197).
2. Jerne, N.K, Perry, W.L.M. The stability of biological standards. Bull. WHO 14: 167-182 (1956).

10. ACKNOWLEDGEMENTS

N/A

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

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