Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Anti- Birch Pollen Serum, Human Research Reagent
NIBSC code: 76/525
Instructions for use
(Version 6.0, Dated 24/07/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This is comprised of a batch of ampoules coded 76/525. Each ampoule contains the residue after freeze drying of approximately 1.0ml 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

No unitage is assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Biological Activity.

The reagent reacts in in vitro assays such as the radioallergosorbent test (RAST), RAST inhibition, crossed radioimmunoelectrophoresis (CRIE) and immuno-blotting with allergens present in extracts of Birch pollen. The reagent was used in the collaborative study to establish the first International Standard for Birch (Betula verrucosa) pollen extract[1].

Bulk Material

The bulk material consisted of donations of plasma from 8 or 9 donors allergic to birch pollen and having IgE-specific antibodies with RAST ratings of between 3 and 4. The collection of plasma samples was carried out by Dr Lars Belin of Gotenborg, Sweden, the plasma donations were pooled and coagulation induced by recalcification. He serum was frozen in a number of containers in solid CO_2 and delivered in person to NIBSC. The pooled serum amounted to approximately 4.3 litres.

Distribution into ampoules

At NIBSC the frozen serum pool was thawed at 4ºC and was made homogeneous and filtered through Millipore membranes to a final pore size of 0.45µm. The filtered serum, maintained at +4ºC, was distributed in 1.0ml aliquots into approximately 4000 ampoules, coded 76/525. The mean weight of liquid contents of 63 checkweight ampoules taken at intervals during the fill was 1.002gm +/- 0.25% (range 0.998 - 1.003gm). The contents of the ampoules were then freeze dried and secondarily desiccated under the conditions normally used for international biological standards[3]. The mean dry weight of ampoule contents was found to be 71.51mg (range, 71.02 - 72.63mg; n=6) and analysis of the atmosphere within the sealed ampoules gave an oxygen value of 0.61% (range, 0.57 - 0.63%;n=3).

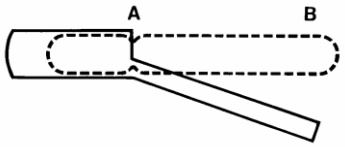
5. STORAGE

Unopened ampoules should be stored at -20°C

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 1.0ml 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

8. STABILITY

Accelerated degradation studies [2] on the contents of unopened freeze dried ampoules of NIBSC Reagent 76/525 have shown no significant loss of potency after storage at temperatures of +20°C and lower for a period of 34 months as tested by RAST inhibition.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities.

Reference Materials should be stored on receipt as indicated on the label.

9. REFERENCES

1. Arntzen, F.C, Wilhelmsen, T.W, Lowenstein, H., Gjesing, B., Maasch, H.J., Stromberg, R., Einarsson, R., Backman, A., Makinen-Kiljunen, S & Ford, A. the international collaborative study on the first international standard of birch (Betula verrucosa) - pollen extract. J. Allergy Clin. Immunol. 83: 66-82 (1989)

2. Jerne, N.K Perry W.L.M. the stability of biological standards. Bull. WHO 14: 167-182 (1956).

3. 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).

10. ACKNOWLEDGEMENTS

Acknowledgements are made to Dr Lars Belin, Department of Allergology, First Medical Service, Sahlgren's Hospital, S-413 45 Goteborg, Sweden.

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

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

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: 0.07 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

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