

Non WHO Reference Material Mannan (C. albicans) Purified NIBSC code: 76/515 Instructions for use (Version 7.0, Dated 24/07/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The reagent is comprised of a batch of ampoules coded 76/515. Each ampoule contains the residue after freeze-drying from ammonium bicarbonate buffer of approx 1.0ml of mannan from disrupted cell walls of Candida albicans as described by Longbottom et al, 1976⁽¹⁾.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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

None assigned

4. CONTENTS

Country of origin of biological material: United Kingdom.

Bulk Material

The reagent was prepared from cells of Candida albicans group A, strain B311 in the blastospore form grown on non-antigenic liquid medium. The cells were centrifuged free of supernatant and washed twice with physiological saline containing 0.05% sodium azide.

The cells were ruptured by pressure at -20°C and differentially centrifuged to produce a crude cytoplasmic extract. The mannan extract was prepared from the washed, disrupted cell wall debris by heat extraction and by precipitation⁽¹⁾.

Distribution Into Ampoules

At NIBSC the extract was filtered through Millipore membranes to a final pore size of $0.22\mu m$ and distributed in 1.0ml volumes at room temperature into approx 500 ampoules, coded 76/515. The mean weight of liquid contents of 15 checkweight ampoules taken at intervals during the fill was $1.002gm \pm 0.00\%$. The contents of the ampoules were then freeze-dried and secondarily desiccated under the conditions normally used for international biological standards⁽³⁾

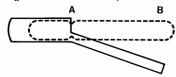
5. STORAGE

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

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

Accelerated degradation studies have shown freeze-dried allergen extracts stored in unopened ampoules at -20°C to be extremely stable over a number of years.

9. REFERENCES

- 1. Longbottom, J. L. Brighton, W. D. , Edge, G., Pepys, J. Antibodies mediating type I skin test reactions to polysaccharide and protein antigens of *Candida albicans*. Clin. Allergy 6:41-49 (1976).
- 2. Jerne, N.K., Perry, W.L.M. The stability of biological standards. Bull. WHO 14:167-182 (1956).
- 3. Campbell, PJ., International Biological Standards and Reference Preparations. II. Procedures used for the production of biological standards and reference preparations. J. Biol. Stand 2:259-267 (1974).

10. ACKNOWLEDGEMENTS

N/A

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:

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

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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				perties	
	Physical appearance: Freeze- dried powder		Corrosive:	No	
	Stable:	Yes	Oxidising:	No	
	Hygroscopic:	No	Irritant:	No	
	Flammable:	No	Handling:	See caution, Section 2	
	Other (specify): material is of biological origin				
	Toxicological properties Effects of inhalation: Not established, avoid inhalation Effects of ingestion: Not established, avoid ingestion				
	Effects of skin abso	Effects of skin absorption: Not established, avoid contact with skin			
	Suggested First Aid				
Inhalation: Seek medical advice					
	ngestion: Seek medical advice				
	Contact with eyes:	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				

15. LIABILITY AND LOSS

biological waste.

appropriate disinfectant followed by water.

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.

Absorbent materials used to treat spillage should be treated as

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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: 0.01g

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No

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