

Non WHO Reference Material Anti-PT S1 subunit Monoclonal Antibody E2E NIBSC code: 99/518 Instructions for use (Version 5.0, Dated 19/04/2017)

This material is not for in vitro diagnostic use.

1. INTENDED USE

Material E2E is a monoclonal antibody which reacts to pertussis toxin S1 subunit. The hybridoma cell line for the production of the monoclonal antibody was established by Drs H. Sato and Y. Sato, National Institute of Infectious Diseases, Tokyo, Japan.

It is intended for use as a research reagent to characterise pertussis toxin.

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

No unitage is assigned to this material.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial contains 400 μ l of frozen material from mouse ascitic fluid. The monoclonal antibody was prepared from pristane-treated mice after intraperitoneal injection with cells of the hybridoma cell line E2E. The ascitic fluid was diluted 1/25 in PBS containing 1% normal mouse serum. This solution was dispensed in 400 μ l aliquots into vials, coded 99/518 and stored at -20°C in the dark.

5. STORAGE

It is recommended that unopened vials, aliquots and diluted material not for immediate use, are stored at -20°C or lower. Repeat freeze-thawing should be avoided. The vials contain no bacteriostat and the preparation should not be assumed to be sterile.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

A suggsted dilution of approximately 1/200 of this solution is recommended for the initial dilution on the ELISA plate. However, this may vary with individual laboratories.

8. STABILITY

Reference materials are held at NIBSC within assured, temperaturecontrolled storage facilities.Reference Materials should be stored on receipt as indicated on the label. They remain valid with the assigned potency and status until withdrawn or amended.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

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UK Official Medicines Control Laboratory

9. REFERENCES

The activities of E2E in immunoblot, ELISA and protection in mice has been reported in: Sato H and Sato Y (1990) Protective activities in mice of monoclonal antibodies against pertussis toxin. Infect. Immun. 58, 3369 - 3374, and Sato, H., Sato, Y. and Ohishi, I. (1991) Comparison of pertussis toxin (PT)-neutralizing activities and mouseprotective activities of anti-PT mouse monoclonal antibodies. Infect. Immun. 59 (10), 3832-3835.

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Dr H Sato, National Institute of Infectious Diseases, Tokyo, Japan for the kind donation of the hybridoma cell line.

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	Corrosive:	No
appearance: Liquid		
Stable:	Oxidising:	No
Yes		
Hygroscopic: No	Irritant:	No
Flammable:	Handling:	See caution, Section 2
No	-	
Other (specify): Contains material of mouse origin		
Toxicological properties		
Effects of inhalation: Not established, avoid inhalation		
Effects of ingestion: Not established, avoid ingestion		
Effects of skin absorption: Not es		blished, 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		



Action on Spillage and Method of Disposal

Spillage of vial 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: 0.4 g Toxicity Statement: Non-toxic Veterinary certificate or other statement if applicable. Attached: No

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