Influenza Reagent
A/Singapore/1/57 (H2N2) Influenza Virus Antigen
NIBSC code: 00/548
Instructions for use
(Version 4.0, Dated 25/01/2024)

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Influenza antigen reagent 00/548 is prepared for single radial-diffusion assay of A/Singapore/1/57 antigens using an appropriate NIBSC antiserum reagent.

2. CAUTION

The material is not of human or bovine origin. This preparation is not for administration to humans or animals

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

The potency of 00/548 is $50 \mu g/ml$.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Antigen reagent 00/548 is prepared from formalin-inactivated, partially purified A/Singapore/1/57 (H2N2) virus which was suspended in PBSA buffer containing 1% (w/v) sucrose and processed for freeze-drying in 1ml volumes as described by Campbell, P.J., Journal of Biological Standardisation,1974, 2, 249-267.

5. STORAGE

Unopened ampoules should be store at -20°C but storage of reconstituted reagent is not recommended.

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 manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freezedried material prior to reconstitution

For all practical purposes each ampoule contains the same quantity of the substances listed above. Reconstitute the total contents of one ampoule of Reagent in 1ml of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solution of freeze-dried material. Antigen reagent 00/548 should be used according to the method described by Wood JM, Schild GC, Newman RW and Seagroatt VA. Journal of Biological Standardisation, 1977, 5, 237-247, with the following modification: it is recommended that Antigen Reagent 00/548 and test A/Singapore/1/57 test antigens should be treated with Zwittergent 3-14 detergent (Calbiochem-Behring, La Jolla, CA, USA) before



single-radial-diffusion assay. Suitable incubation conditions are as follows:

 $450\mu l$ of antigen are added to $50\mu l$ of 10% (w/v) Zwittergent detergent and incubated in covered containers for 30 minutes at room temperature (20-25°C). Dilutions of detergent treated antigens are then added to wells in single radial diffusion immunoplates and incubated at 20-25°C.

Antigen Reagent 00/548 should be used to assay A/Singapore/1/57 antigens using antiserum Reagent 00/440.

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.

NIBSC follows the policy of WHO with respect to its reference materials.

Users of the material wishing to refer to the declared ampoule content for use in quantitative or semi-quantitative assay methods should note that the stated content of the material is based on a small collaborative study involving WHO Essential Regulatory Laboratories (ERLs) or Official Medicines Control Laboratories (OMCLs). Studies of recovery and stability of similar antigen preparations indicate that that recovery after ampouling is likely to be close to quantitative, and that no significant loss of content would be expected during storage over at least a 10 year period.

9. REFERENCES

N/A

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:

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

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Medicines & Healthcare products Regulatory Agency



Physical and Chemical properties			
Physical appearance:		Corrosive:	No
Freeze-dried powder			
Stable: Yes		Oxidising:	No
Hygroscopi No		Irritant:	No
c:			
Flammable: No		Handling: See caution, Section 2	
Other Contains inactivated influenza virus			
(specify):			
Toxicological properties			
Effects of inhalation: Not		established, avoid inhalation	
-		established, avoid ingestion	
Effects of skin	Not established, avoid contact with		
absorption:	skin		
Suggested First Aid			
Inhalation: Seek medical advice			
Ingestion: Seek medical advice			
Contact with Wash with copious amounts of water. Seek			
eyes: medical advice			
Contact with Wash thoroughly with water.			
skin:			
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 app	ropria	te disinfectant	followed by water.
Absorbent materials used to treat spillage should be treated as			

15. LIABILITY AND LOSS

biological waste.

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: 1 g

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No