Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Antigen A/Brazil/11/78 (H1N1)
NIBSC code: 83/550
Instructions for use
(Version 4.0, Dated 29/03/2008)

1. INTENDED USE

Influenza antigen reagent 83/550 is prepared for the single radial diffusion assay of A/Brazil/11/78 antigens using an appropriate NIBSC antiserum reagent.

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

4. CONTENTS

Country of origin of biological material: United Kingdom.
Antigen Reagent 83-550 is prepared from partially purified, beta propiolactone-inactivated influenza virus, suspended in PBS containing 1% (w/v) sucrose and processed for freeze-drying in 1ml volumes as described by Campbell PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The mean weight of 66 ampoules, test weighed was 1.003g (‡0.38%).

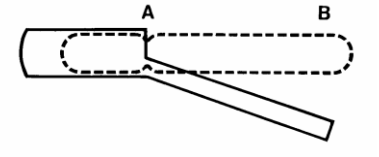
The reagent has been inactivated following validated procedures used to produce human influenza vaccine that is registered in the EU. This inactivated reagent has been shown to be free from residual infectious virus by testing according to the European Pharmacopeia Compendial Assay (monograph 0158).

5. STORAGE

-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 material
Reconstitute the total contents of one ampoule of Reagent with 1ml of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solution of the freeze-dried material. The solution of the total contents of the ampoule will contain 29 micrograms of haemagglutinin antigen activity. Antigen Reagent 83-550 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:
a) Antigen Reagent 83-550 and test A/Brazil/11/78 virus antigens should be incubated with Mulgofen BC720 detergent (alternative name Emulphogene BC720) before preparing sutiable dilutions for the single-radial diffusion assay. Suitable incubation conditions are as follows: 450 microlitres of antigen are added to 50 microlitres of 20% (v/v) Mulgofen detergent and incubated in covered containers for 30 minutes at room temperature (approx. 20oC). Dilutions of detergent –treated antigens are prepared and suitable volumes are added to wells in single-radial-diffusion immunoplates.
b) Antigen reagent 83-550 replaces the previous A/Brazil/78 antigen reagent 79-560. Reagent 79-560 should no longer be used due to its instability.

8. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

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

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

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

None

10. ACKNOWLEDGEMENTS

None

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 inactivated Influenza virus	
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: 1g
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
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