Medicines & Healthcare products Regulatory Agency



Influenza Reagent Influenza antigen A/Anhui/1/05 (H5N1) IBCDC-RG6 NIBSC code: 07/290 Instructions for use (Version 2.0, Dated 20/02/2008)

1. INTENDED USE

Influenza antigen reagent 07/290 is prepared for single radial diffusion assay of A/Anhui/1/05 antigens using a suitable 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

Antigen reagent 07/290 contains 99µg haemagglutinin/ml

4. CONTENTS

Country of origin of biological material: United Kingdom.

Antigen reagent 07/290 is prepared from β -propiolactone inactivated, partially purified A/Anhui/1/05 virus (IBCDC RG-6), which was suspended in PBSA buffer containing 1% (w/v) sucrose and processed for freezedrying in 1ml volumes as described by Campbell, P.J, Journal of Biological Standardization, 1974, 2, 249-267.The contents of the ampoules should not be assumed to be sterile.

5. STORAGE

Unopened ampoules should be store at -20oC 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 freeze-dried 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 with 1ml of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solution of freeze-dried material. To remove the reconstituted material from the ampoule, it is necessary to use some form of transfer pipette rather than a volumetric pipette. Antigen Reagent 07/290 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 07/290 and test A/Anhui/1/05 virus 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: 150µl of antigen is diluted in 300µl of phosphate buffered saline, added to 50 µl of 10% (w/v) Zwittergent detergent and incubated in covered containers for

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 30 minutes at room temperature (20-250 C). Dilutions of detergent treated antigens are then added to wells in single-radial-diffusion immunoplates and incubated at 20-250 C.

Antigen Reagent 07/290 should be used to assay A/Anhui/1/05 antigens using an NIBSC antiserum reagent.

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.

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

9. REFERENCES

Not applicable

10. ACKNOWLEDGEMENTS Not applicable

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 appearance: | | | Corrosive: | No | |
| Freeze dried powder | | | | | |
| Stable: | Yes | | Oxidising: | No | |
| Hygroscopic: | No | | Irritant: | No | |
| Flammable: | No | | Handling:Se | e 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 | | | al advice | | |
| Ingestion: Seek medical advice | | | | | |

Medicines & Healthcare products Regulatory Agency



| Contact with eyes: | Wash with copious amounts of water. Seek medical advice | | | |
|--|---|--|--|--|
| Contact with skin: | Wash thoroughly with water. | | | |
| Astismum Onillana and Mathed of Dismonal | | | | |

Action on Spillage and Method of Disposal

Spillage of 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: 0.1g Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable. Attached: No

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