Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Antigen A/New Caledonia/20/99 (IVR-116)
NIBSC code: 03/258
Instructions for use
(Version 4.0, Dated 19/03/2008)

1. INTENDED USE

Influenza antigen reagent 03/258 is prepared for single radial diffusion assay of A/New Caledonia/20/99 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

Antigen Reagent 03/258 contains 52 micrograms of haemagglutinin antigen activity.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Antigen Reagent 03/258 is prepared from formalin-inactivated, partially purified A/New Caledonia/20/99 virus (IVR-116), 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 Standardization, 1974, 2, 249-267. The mean weight of 78 ampoules, test weighed was 1.01g with a coefficient of variation of 0.10%.

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

-20ºC

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 material

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. Antigen Reagent 03/258 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 03/258 and test A/New Caledonia/20/99 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:
450 microlitres of antigen are added to 50 microlitres 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 03/258 should be used to assay A/New Caledonia/20/99 antigens using an NIBSC antiserum reagent.

No attempt should be made to weight out any portion of the freeze-dried material. Unopened ampoules should be store at -20% but storage of reconstituted reagent is not recommended. To remove the reconstituted material from the ampoule, it is necessary to use some form of transfer pipette rather than a volumetric pipette. The contents of the ampoules should not be assumed to be sterile.

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

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
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

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

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: White 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. LOSS AND LIABILITY

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

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