



Influenza Reagent
Influenza Antigen A/Darwin/6/2021 (IVR-227) (H3N2)
NIBSC code: 21/314
Instructions for use
(Version 2.0, Dated 20/12/2021)

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1. INTENDED USE

Influenza antigen reagent 21/314 is prepared for single radial diffusion assay of A/Darwin/6/2021 (IVR-227) egg-derived 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.

3. UNITAGE

The estimated potency value of 21/314 is 39 µg/ml.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Antigen reagent 21/314 is prepared from formalin inactivated, partially purified Influenza antigen A/Darwin/6/2021 (IVR-227) virus grown in eggs, which was suspended in PBSA buffer containing 1% (w/v) sucrose and processed for freeze drying as described in:

http://www.who.int/biologicals/reference_preparations/establishment/en/index.html

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 Pharmacopoeia 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

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 manufacturers 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. Antigen 21/314 should be used according to the method described by Wood, JM, Schild, GC, Newman RW and Seagrott, VA, Journal of Biological Standardisation, 1977, 5, 237-247, with the following modification:

It is recommended that antigen reagent 21/314 and test A/Darwin/6/2021 (IVR-227) 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.

Reagent 21/314 should be used to assay A/Darwin/6/2021 (IVR-227) antigens using an appropriate NIBSC antiserum reagent.

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

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. 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