Medicines & Healthcare products Regulatory Agency



Influenza Reagent Influenza antigen A/Texas/50/2012 (H3N2)(NYMCX-223) NIBSC code: 13/112 Instructions for use (Version 2.0, Dated 21/06/2013)

1. INTENDED USE

Influenza antigen reagent 13/112 is prepared for single radial diffusion assay of A/Texas/50/2012 (NYMCX-223) 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 13/112 has an estimated potency value of 74µgHA/ml.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Antigen reagent 13/112 is prepared from β -propriolactone inactivated, partially purified A/Texas/50/2012 (NYMCX-223) virus which was suspended in PBSA buffer containing 1% (w/v) sucrose and processed for freeze drying in 1ml volumes as described in:

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

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 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 forcomplete solution of freeze dried material. antigen 13/112 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 13/112 and test A/Texas/50/2012 (NYMCX-223) virus antigens should be treated with Zwittergent 3-14 detergent (Calbiochem-Behring, La Jolla, CA, USA) before single single radial diffusion assay. Suitable incubation conditions are as follows:

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

450 microlitres of antigen are added to 50 microlitres of 10% (w/v) Zwittergent dteregent 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 13/112 should be used to assay A/Texas/50/2012 (NYMCX-223) antigens using an appropriate 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

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 appearance: White powder		Corrosive:	No		
	Yes		Oxidising:	No	
	No		Irritant:	No	
Flammable: No		Handling:Se	e caution, Section 2		
Other (specify):	Contains	s inact	ivated influenz		
	Toxic	ologic	al properties		
Effects of inhalation:		Not	Not established, avoid inhalation		
Effects of ingestion:		Not	ot established, avoid ingestion		
Effects of skin absorption:		Not	ot established, avoid contact with skin		
	Sug	geste	d First Aid		
Inhalation: Seek medical advice					
Ingestion: Seek medical advice					
Contact with eyes:	Wash medic			s of water. Seek	
Contact with skin:	Wash	thorou	ighly with wate	r.	
Action of	on Spill	age ai	nd Method of	Disposal	
Spillage of contents	should b	e take	en up with abso	orbent material	
wetted with an appro	priate d	isinfec		ea with an appropriate	
disinfectant followed					
Absorbent materials biological waste.	used to	treat s	spillage should	be treated as	

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 WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory