Medicines & Healthcare products Regulatory Agency



Influenza Reagent Influenza Virus Infectious B/Maryland/15/2016 NIBSC code: 17/164 Instructions for use (Version 2.0, Dated 04/04/2018)

1. INTENDED USE

Reagent 17/164 is prepared from B/Maryland/15/2016 which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The derivation and known passage history of B/Maryland/15/2016 is attached

CAUTION 2.

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

No unitage is assigned to this material

CONTENTS

Country of origin of biological material: United Kingdom. Each ampoule contains 250µl (nominal) of infectious influenza virus as allantoic fluid from SPF embryonated hen's eggs.

5. STORAGE

Store in the dark at -20°C or below

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

DIRECTIONS FOR OPENING 6.

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

Reconstitute the contents of one ampoule of reagent with 250µl of sterile distilled water. Leave for a minimum of 5 minutes before use to allow for complete solution of freeze-dried material. A range of dilutions (e.g. 10⁻³ to 10⁻⁵) should be made in a suitable medium for initial cultivation.

8. STABILITY

Reference Materials should be stored on receipt as indicated on the label.

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

REFERENCES 9.

NA

10. ACKNOWLEDGEMENTS

NA

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UK Official Medicines Control Laboratory

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		
white powder						
Stable:	Yes		Oxidising:	No		
Hygroscopic:	No		Irritant:	No		
Flammable: No		Handling:See caution, Section 2				
Other (specify): Live influenza virus						
Toxicological properties						
Effects of inhalation:		Likelihood of influenza virus infection				
Effects of ingestion:		Not established, avoid ingestion				
Effects of skin absorption:		Not established, avoid contact with skin				
	Sug	geste	ed First Aid			
Inhalation:	Seek r	Seek medical advice				
Ingestion:	Seek medical advice					
Contact with eyes:	Wash	Wash with copious amounts of water. Seek				
medical advice						
Contact with skin:	Wash	thorou	ighly with water			
Action on Spillage and Method of Disposal						
Spillage of contents wetted with an appr						

appropriate virucidal agent followed by water.

Absorbent materials used to treat spillage should be treated as

biologically hazardous 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: 0.25g per ampoule				
Toxicity Statement: Non-toxic				
Veterinary certificate or other statement if applicable.				
Attached: No				

Derivation of B/Maryland/15/2016

Passage	Lot	Laboratory
E1-E3		Unknown
E4	3025628112	CDC, Atlanta, USA
E5	42800	NIBSC, Hertfordshire, UK

Sterility: No visible contamination was detected in a variety of media (tryptose soya broth, thioglycolate broth, Sabouraud's broth and blood agar plates) after 14 days incubation.

The HA and NA sequence of this virus has been sequenced and is available on GISAID with the accession number EPI_ISL_281223.