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Influenza Reagent Influenza Virus Infectious NYMC X-183 NIBSC code: 09/248 Instructions for use (Version 2.0, Dated 26/01/2010)

1. INTENDED USE

Reagent 09/248 is prepared from NYMC X-183 (A/Wisconsin/15//2009 H3N2 x A/PR/8/34 H1N1) which was processed for freeze drying in 250 μl volumes as described by Campbel, PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The known passage history of NYMC X-183 is attached

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

No unitage is assigned to this material

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains 250µl (nominal) of infectious influenza virus as freeze dried allantoic fluid from embryonated SPF 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

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 cutivation.

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

ACKNOWLEDGEMENTS 10.

NA

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

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	e 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				
Suggested First Aid						
Inhalation:	Inhalation: Seek medical advice					
Ingestion:	ngestion: Seek medical advice					
Contact with eyes:	ntact with eyes: Wash with copious amounts of water. Seek					
medical advice						
Contact with skin:	Contact with skin: Wash thoroughly with water.					
Action on Spillage and Method of Disposal						

Spillage of contents should be taken up with absorbent material wetted with a virucidal agent. Rinse area with an 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

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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: NA

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable. Attached: No

Derivation of NYMC X-183

Passage	Lot	Laboratory
E1-E9		New York Medical College, USA
E10	E5868	New York Medical College, USA
E11 (SPF)	32060	NIBSC, Hertfordshire, UK

Derivation of NYMC X-183 Hy A/Wisconsin/15/2009 (H3N2) with A/PR/34 (6 genes)

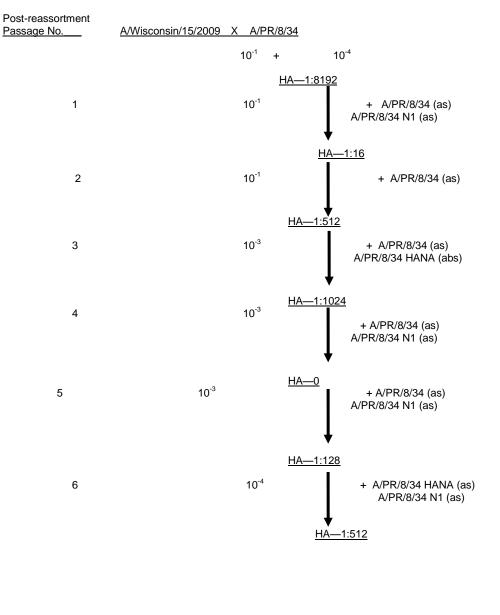
National Institute for Biological Standards and Control, Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory

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High Yield A H3N2 Reassortant (6:2)

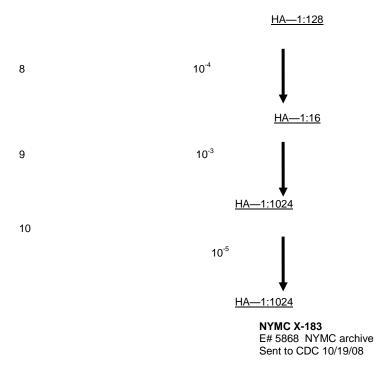
Exper. # 4644 III 9/19/09 A/Wisconsin/15/2009 CDC# 2009023351 E2(8/7/09) HA: 64



7 10⁻⁶

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HA and NA identified as A/Wisconsin/15/2009 serologically by HI and NI tests and by RT-PCR/RFLP analysis. --PB2, PB1, PA, NP, M and NS genes were identified as A/PR/8/34 by RT-PCR/RFLP analysis. Therefore X-183 is a 6:2 reassortant (6 PR/8 genes and 2 genes HA and NA from A/Wisconsin).

SPAFAS eggs used for all reassortant passages.

All HA titers were tested using chicken red blood cells at room temp.

Virus seed was shown to be sterile. Sterility testing was performed by streaking the sample on blood agar plates and incubating for 48 hours at 37° C.

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