Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
INFLUENZA VIRUS INFECTIOUS NYMC X-161B
NIBSC code: 06/242
Instructions for use
(Version 3.0, Dated 09/07/2021)

1. INTENDED USE

Reagent 06/242 is prepared from NYMC X-161B which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The known passage history of NYMC X-161B is attached.

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

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 allantoic fluid from embryonated hen's eggs

5. STORAGE

Store in the dark at -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

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

No stability data is available for this mater

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

9. REFERENCES

NA

10. ACKNOWLEDGEMENTS

NA

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: Freezen dried powder	Corrosive: No
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 skinntact 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 virucidal agent. Rinse area with an appropriate virucidal agent 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.

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

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: 0.25 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

Derivation of NYMC X-161B (Post mixed infection)

Passage	Lot	Laboratory
E1 – E7		NYMC, New York, USA
E8	E#5652	NYMC, New York, USA
E9	24980	NIBSC, Hertfordshire, UK

Derivation of NYMC X-161B
A/Wisconsin/67/2005 (H3N2) with A/PR/8/34 M and NP

High Yield A Reassortant

Exper. # 4606 II (2/7/06)
A/Wisconsin/67/2005 (CDC#2005756250) recd. from CDC 2/3/06
SpfCK 3E3 (1/06/06) HA-1:64

Post-reassortant
Passage No.___ A/Wisconsin/67/2005 X A/PR/8/34

10^{-1} + 10^{-5}

HA—C*1:4096

1 10^{-1} ***(e8)*** + A/PR/8/34 N1 antisera (as)
A/PR/8/34 antisera (as)

HA—C 1:128

2 10^{-1} + A/PR/8/34 N1 antisera (as)
A/PR/8/34 HANA antibodies (ab)
(ab)

HA—C 1:256

3 10^{-1} + A/PR/8/34 N1 antisera (as)
A/PR/8/34 HANA antibodies (ab)

HA—C 1:256

4 10^{-1}

HA—C 1:1024

5 10^{-1}

HA—C 1:256

6 10^{-1}

HA—C 1:128

7 10^{-7}

HA—C 1:512

8 10^{-4}

HA—C 1:1706 5
(E#5652—NYMC archive)
→→→NYMC X-161B sent to CDC 4/18/06

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Appendix (derivation received from NYMC)

*C, chicken red blood cells
HA and NA identified as A/Wisconsin/67/2005 serologically by HI and NI tests and by RT-PCR/RFLP analysis of HA and NA genes.
M and NP genes identified as A/PR/8/34 by RT-PCR/RFLP analysis.
SPAFAS eggs used exclusively for all passages.