Influenza Reagent Influenza Virus Infectious A/Netherlands/00007/2021 (H3N2) NYMC X-377 NIBSC code: 22/158 Instructions for use (Version 1.0, Dated 18/08/2022)



Reagent 22/158 is prepared from NYMC X-377 (H3N2), a ressortant of A/Netherlands/00007/2021 and A/PR/8/34, which was processed in 250µl volumes as liquid stock. The known passage history of NYMC X-377 is attached.

2. CAUTION

The material is not of human or bovine origin. This preparation is not for administration to humans or animals

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 vial contains 250µl (nominal) of infectious influenza virus as allantoic fluid from SPF embryonated hen's eggs.

5. STORAGE

Store in the dark at -70°C or below.

Material type: Liquid - will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

Ready to use.

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.

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

(EC) No 12/2/200	EC) No 1272/2008: Not applicable or not classified					
Physical and Chemical properties						
Physical appearance: Clear liquid			Corrosive:	No		
	Yes		Oxidising:	No		
Hygroscopi c:	No		Irritant:	No		
Flammable:	lammable: No			ee caution, Section 2		
Other Live influenza virus (specify):						
Toxicological properties						
Effects of inhalation: Like			lihood of influ	enza virus infection.		
Effects of ingestion:		Not established, avoid ingestion				
Effects of absorption:	skin	Not skin	established,	avoid contact with		
Suggested First Aid						
Inhalation: Seek medica			al advice			
Ingestion:	estion: Seek medical advice					
Contact with eyes:		Vash with copious amounts of water. Seek nedical advice				
Contact with skin:	Wash	thoro	ughly with wa	iter.		
Action on Spillage and Method of Disposal						

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: 0.25g per vial.

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No

Passage history of NYMC X-377 (H3N2)

Cumulative number of passages	Passage numbers at each stage	Lot	Laboratory
E3	E3	211061	Crick Institute, UK
E4	E3/E1	unknown	NYMC, USA
E12	E3/E1/E8	#6516	NYMC, USA
E13	E3/E1/E8/E1	47070	NIBSC, 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 is available at GISAID with the accession number EPI_ISL_14267164.



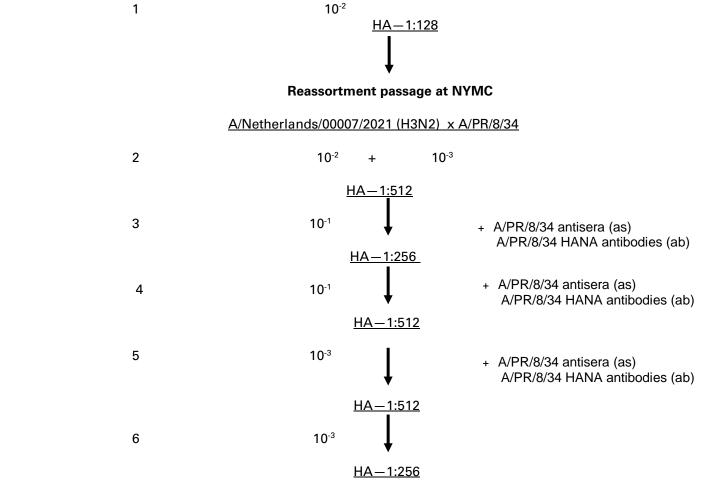
Derivation of NYMC X-377 High Yield H3N2 Reassortant (5:3) with A/PR/8/34 PB2, PA, NP, M, and NS genes and A/Netherlands/00007/2021 HA, NA and PB1 genes

Experiment # 4883(2/8/2022) A/Netherlands/00007/2021 (H3N2) 211061 E3(Am2Al1) GP 16 (10^5) 21/09/2021

Passage No.

Passages prior to receipt at NYMC - 3

Passages at New York Medical College

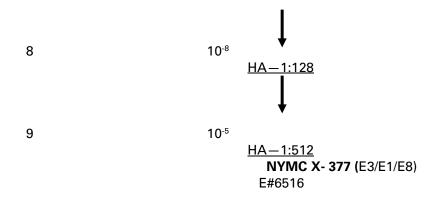


10-8

HA - 1:128

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HA, NA and PB1 genes were identified as A/Netherlands/00007/2021 by RT-PCR/RFLP gene analysis. PB2, PA, NP, M and NS genes were identified as A/PR/8/34 by RT-PCR/RFLP analysis.

The HA yield for X-377 was shown to be 5.5 ug/ml by UPLC analysis. The HA yield for A/Netherlands/00007/2021 (H3N2) was 3.8 ug/ml by UPLC analysis

SPF eggs were used for all reassortant passages.

All HA titers were tested using guinea pig red blood cells (cRBC) at room temperature.

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.