



Reagent 20/264 is prepared from X-341 + 1P (H3N2) which was processed in 250 μ l volumes as liquid stock. The derivation and known passage history of X-341 + 1P (H3N2) 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 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

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 should be stored on receipt as indicated on the

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

9. **REFERENCES**

NA

ACKNOWLEDGEMENTS 10.

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/

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**



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

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		
Clear liquid					
Stable: Y	es	Oxidising:	No		
Hygroscopic: N	О	Irritant:	No		
Flammable: N	0	Handling:See c	aution, 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:	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 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 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 Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or 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 X-341+1P(H3N2)

Cumulative number of passages	Passage numbers at each stage	Lot	Laboratory
E1-E7	E7	Unknown	Unknown
E8-E17	E7/E10	E#6441	NYMC, USA
E18	E7/E10/E1	45780	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_882956.





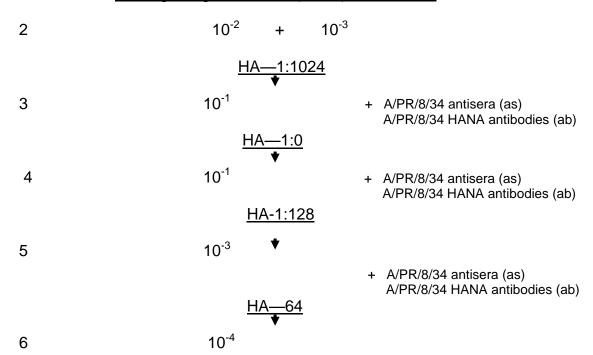
Derivation of NYMC X-341 +1P

A/Hong Kong/2671/2019 (H3N2) with A/PR/8/34
High Yield A H3N2 Reassortant (2:6)
with A/PR/8/34 M and NP genes and
A/Hong Kong/2671/2019 HA,NA,PB1,PB2,PA and NS genes

Exper. # 4850 A/Hong Kong/2671 /2019 H3N2 #193956 E7 (Am3Al 4) GP32(10⁻⁵) 8/10/2019

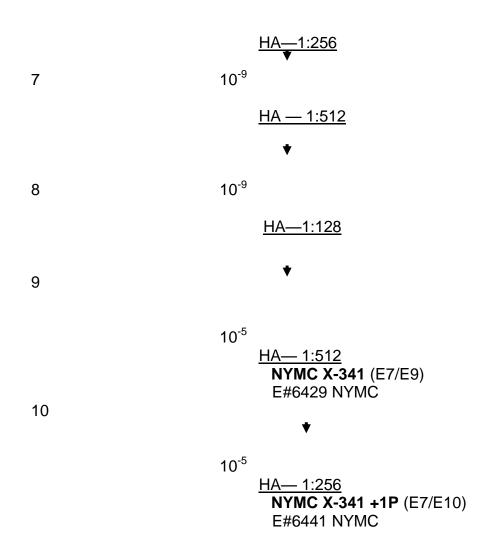
Passages at New York Medical College

A/Hong Kong/2671/2019 (H3N2) x A/PR/8/34



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The HA yield of X-341 was shown to be 4.2 ug/ml by UPLC analysis. The HA yield for A/Hong Kong/2671/2019 was 4.2 ug/ml by UPLC analysis.

HA ,NA,PB1,PB2,PA and NS genes were identified as A/Hong Kong/26712019 by RT-PCR/RFLP gene analysis. M and NP genes were identified as A/PR/8/34 by RT-PCR/RFLP analysis.

SPF eggs were used for all reassortant passages.

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.



