Influenza Reagent
Influenza Virus Infectious X-357A (H3N2)
NIBSC code: 21/122
Instructions for use
(Version 7.0, Dated 27/04/2021)

1. INTENDED USE
Reagent 21/122 is prepared from X-357A (H3N2) (A/Perth/20/2020
(H3N2) x PR/8/34) which was processed in 250μl volumes as liquid stock.
The derivation and known passage history of X-357A (H3N2) 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 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
label.

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/

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
referred to, 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

![Material Safety Data Sheet](image)

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

<table>
<thead>
<tr>
<th><strong>Country of origin for customs purposes</strong></th>
<th><strong>United Kingdom</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
</tbody>
</table>

| **Net weight:** | **0.25g per vial** |

<table>
<thead>
<tr>
<th><strong>Toxicity Statement:</strong></th>
<th><strong>Non-toxic</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Veterinary certificate or other statement if applicable.</strong></td>
<td><strong>Attached: No</strong></td>
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</tbody>
</table>

### Passage history of X-357A (H3N2)

<table>
<thead>
<tr>
<th>Cumulative number of passages</th>
<th>Passage numbers at each stage</th>
<th>Lot</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1-E5</td>
<td>E3/E2</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td>E6-E14</td>
<td>E3/E2/E9</td>
<td>E#6468</td>
<td>NYMC, USA</td>
</tr>
<tr>
<td>E15</td>
<td>E3/E2/E9/E1</td>
<td>46000</td>
<td>NIBSC, UK</td>
</tr>
</tbody>
</table>

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 accession number EPI_ISL_1585693
Derivation of NYMC X-357A High Yield H3N2 Reassortant (6:2) with A/PR/8/34 PB1, PB2, PA, NP, NS and M genes and A/Perth/20/2020 HA and NA genes

Experiment # 4866 II (11/10/2020)
A/Perth/20/2020 #3000827645 1/29/20
E3/E2 HA 128 GP

Passages prior to receipt at NYMC -5

Passages at New York Medical College

Passage No.   1

10^{-2}  
HA—-1:8
  
Reassortment passage at NYMC

A/Perth/20/2020 (H3N2) x A/PR/8/34

2

10^{-2} + 10^{-3}

HA—1:1024

3

10^{-1}
HA—1:512

+ A/PR/8/34 antisera (as)
A/PR/8/34 HANA antibodies (ab)

4

10^{-1}
HA—1:128

+ A/PR/8/34 antisera (as)
A/PR/8/34 HANA antibodies (ab)

5

10^{-3}

HA—0

+ A/PR/8/34 antisera (as)
A/PR/8/34 HANA antibodies (ab)

6

10^{-4}

HA—1:512
HA and NA genes were identified as A/Perth/20/2020 by RT-PCR/RFLP gene analysis. PB1, PB2, PA, NS, NP and M genes were identified as A/PR/8/34 by RT-PCR/RFLP analysis.

The HA yield for X-357A was shown to be 3.8 ug/ml by UPLC analysis. The HA yield for A/Perth/20/2020 was 2.5 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.