1. INTENDED USE

Reagent 22/134 is prepared from NYMC BX-107A (B/Austria/1359417/2021 (B-Victoria Lineage) x NYMC BX-42) which was processed in 250µl volumes as liquid stock. The known passage history of BX-107A 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.

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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Clear liquid</td>
<td>Effects of inhalation: Likelihood of influenza virus infection.</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Live influenza virus</td>
<td></td>
</tr>
</tbody>
</table>

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 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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*</th>
<th>United Kingdom</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. |
| Toxicty Statement: | Non-toxic |
| Veterinary certificate or other statement if applicable. | Attached: No |

Passage history of NYMC BX-107A

<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-E3</td>
<td>E3</td>
<td></td>
<td>The Francis Crick Institute, UK</td>
</tr>
<tr>
<td>E4-E11</td>
<td>E2/E11</td>
<td>E#6514</td>
<td>NYMC, USA</td>
</tr>
<tr>
<td>E12</td>
<td>E3/E11/E1</td>
<td>46970</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 the accession number EPI_ISL_13633122.
Derivation of NYMC BX-107A
B/Austria/1359417/2021 (Victoria lineage) - like High Yield Reassortant (1:1:6)
B/Lee/40: B/Panama/45/90: B/Austria/1359417/2021
with B/Lee/40 NP gene; B/Panama/45/90 PB2 gene;
B/Austria/1359417/2021 PB1, PA, HA, NA, M, NS genes

Exper. # 4882 11/23/2021
B/Austria/1359417/2021 (Victoria lineage; V1A3del) The Francis Crick Institute
E3 (Am2Al1) Is2 HA:128-256 (TK) 22/03/2021 KC

NYMC BX-42: Hybrid strain with B/Panama/45/90 PB1, PB2, PA, HA, NA, NS and B/Lee/40 NP and M genes

Passage No. 1 to 3

Passages prior to receipt at NYMC (E3)

Passage at NYMC

1
pre-reassortment passage

B/Austria/1359417/2021 X NYMC BX-42

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

HA—1:512
+ B/Panama/45/90 HANA antibodies

3
10^{-3}

HA—1:1024

4
10^{-3} + B/Panama/45/90 HANA ab

HA—1:512

5
10^{-3} + B/Panama/45/90 HANA ab

HA—1:1024
HA and NA identified as B/Austria/1359417/2021 by RT-PCR/RFLP analysis of HA and NA genes. RT-PCR/RFLP analysis also identified NP gene as B/Lee/40; PB2 gene as B/Panama/45/90; PB1, PA, M and NS genes (in addition to HA and NA) as B/Austria/1359417/2021.

SPAFAS eggs were used for all passages.
HA titers were performed using chicken red blood cells at room temp.
Virus seeds were shown to be sterile by streaking samples on sheep blood agar plates and incubating for 48 hours at 37 °C.