



Reagent 21/158 is prepared from BX-93B (B-Victoria Lineage) which was processed in 250µl volumes as liquid stock. The derivation and known passage history of BX-93B (B-Victoria Lineage) 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:	Yes		Oxidising:	No		
Hygroscopic:	No		Irritant:	No		
Flammable:	No		Handling:See	e 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 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 BX-93B (B-Victoria Lineage)

Cumulative number of passages	Passage numbers at each stage	Lot	Laboratory
E1-E3	E3	Unknown	Unknown
E4-E13	E3/E10	E#6463	NYMC, USA
E14	E3/E10/E1	46100	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.





Derivation of NYMC BX-93B

B/Kanagawa/AC1867/2019 (Victoria lineage) - like Reassortant (2:3:3)
B/Lee: B/Panama: B/Kanagawa

with B/Lee/40 NP and M genes; B/Panama/45/1990 PB1, PB2, NS genes and B/Kanagawa/AC1867/2019 HA, NA and PA genes

Exper. # 4868 12/07/20

B/Kanagawa/AC1867/2019 (Victoria lineage) Received from the NIID in Sept 2019

Passage*: E3 HA titer: 512

NYMC BX-42: Hybrid strain with B/Panama/45/1990 PB1, PB2, PA, NS, HA, NA and B/Lee/40 NP and M genes

Passage No. Passages prior to receipt at NYMC (E3) Passage at NYMC 1 pre-reassortment passage B/Kanagawa/AC1867/2019 X NYMC BX-42 10⁻³ 10⁻³ 2 HA-1:512 +B/panama HANA antibodies (ab) 3 10⁻³ HA-1:256 + B/panama HANA antibodies (ab) 10⁻³ + B/panama HANA antibodies (ab) 5 -1:1024 10⁻³ 6 HA-1:1024 10⁻³ 7 HA-1:1024

10⁻⁸

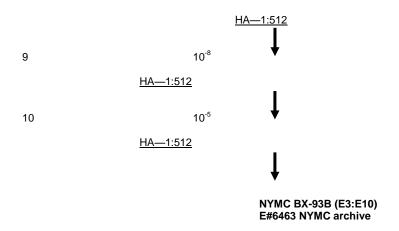
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8





BX-93B: HA, NA and PA identified as B/Kanagawa/AC1867/2019 by RT-PCR/RFLP analysis. NP and M genes are from B/Lee/40; PB1, PB2 and NS genes are from B/Panama/45

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.

UPLC result indicated that HA yield from BX-93B is 0.96 fold vs wild type.

UK Official Medicines Control Laboratory