



1. INTENDED USE

Reagent 21/216 is prepared from BVR-25 which was processed in 250µl volumes as liquid stock. The derivation and known passage history of BVR-25 (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/

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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 class

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 infl					
Toxicological properties					
Effects of inhalation: Like		lihood 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	thoroug	ghly with wate	r.		
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 BVR-25 (B-Victoria Lineage)

Cumulative number of	Passage numbers at each stage	Lot	Laboratory
passages			
E1-E4	E4	Unknown	Unknown
E5-E13	E4/E9	LOT 497C	Seqirus, Australia
E14	E4/E9/E1	46500	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_4458445.





REPORT

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PASSAGE HISTORY:		
Mixed infection passage: (E4/D1)	B/Victoria/2110/2019 wild type virus @10 ⁻³ x B/Brisbane/46/2015 @10 ⁻⁵ ↓	HA titre = 39
1st Antiserum Passage	Inoculum @ 10-3 with Mab to	HA titre ≥ 1689
(E4/D2)	B/Brisbane/60/2008 ↓	
2 ^{ud} Antiserum/1st Limit	Inoculum @ 10-9 with Mab to	HA titre = 844
Dilution Passage** (E4/D3)	B/Brisbane/60/2008	
	+	
3 rd Limit Dilution Passage (E4/D4)	Inoculum @ 10-9	HA titre = 1040
	↓	
4th Limit Dilution Passage (E4/D5)	Inoculum @ 10-7	HA titre ≥ 1256
	1	
5th Limit Dilution Passage (E4/D6)	Inoculum @ 10-9	HA titre ≥ 1749
	1	
6th Limit Dilution Passage	Inoculum @ 10-6	HA titre ≥ 1154
(E4/D7)		
	↓	
7th Limit Dilution Passage	Inoculum @ 10-8	HA titre ≥ 1810
(E4/D8)		
04 T : 1 TO 1	*	
8th Limit Dilution Passage Lot 497C (E4/D9) BVR-25	Inoculum @ 10-4	Mean HA titre = 403

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REPORT

Total number of passages post mixed infection = 8

Total number of passages since this virus was received from an approved laboratory = 9

HA titres were determined using fowl red blood cells at room temperature.

** Virus sample diluted to 10-3 dilution was mixed with Mab to B/Brisbane/60/2008 and incubated for 1 hour at room temperature. Incubated virus/MAb sample was serially diluted and inoculated into eggs at indicated dilution.

TESTING OF B/VICTORIA/2110/2019 (BVR-25) INFLUENZA VIRUS

Test	Result			
Genotype (by DNA sequencing)	1:7 (B/Brisbane/46/2015: B/Victoria/2110/2019) Reassortant B/Victoria/2110/2019 (wild type virus) HA, NA, PB1, PB2, PA, NP and NS genes were detected B/Brisbane/46/2015 (HGP) Matrix (M) gene was detected.			
	Gene	B/Victoria/2110/2019	B/Brisbane/46/2015	
	HA	1	X	
	NA	√	X	
	PB1	√	X	
	PB2	√	X	
	PA	√	X	
	NP	√	X	
	M	X	V	
	NS	√	X	

^{√ -} positive by Sequencing

Disclaimer:

The material i.e. high growth reassortant virus BVR-25 and the information provided in this derivation report are provided on an "as is" basis and as such without any warranty or representation of any kind (expressed or implied) including, without limitation, of satisfactory quality or fitness for a particular purpose.

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X - negative by Sequencing