

Influenza Reagent Influenza Virus Infectious IVR-208 (H3N2) NIBSC code: 21/380 Instructions for use (Version 1.0, Dated 03/03/2022)

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#### 1. INTENDED USE

Reagent 21/380 is prepared from IVR-208 (H3N2) which was processed in  $250\mu$ I volumes as liquid stock. The known passage history of IVR-208 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  $250\mu I$  (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;

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



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#### 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

Physical and Chemical properties					
Physical appearance:		Corrosive:	No		
Clear liquid					
Stable: Yes	5	Oxidising:	No		
Hygroscopi No		Irritant:	No		
c:					
Flammable: No		Handling: See	caution, Section 2		
Other Liv	Live influenza virus				
(specify):					
Toxicological properties					
Effects of inhalation: Likel		lihood of influenza virus infection.			
Effects of ingestion: Not		established, avoid ingestion			
Effects of absorption:	skin Not skin		void contact with		

#### Suggested First Aid

Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with	Wash with copious amounts of water. Seek
eyes:	medical advice
Contact with	Wash thoroughly with water.
skin:	

#### 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

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 IVR-208 (H3N2)

Cumulative number of passages	Passage numbers at each stage	Lot	Laboratory
E7	Ε7	SL100330	VIDRL, Australia
E17	E7/E10	VI-1651	Seqirus, Australia
E18	E7/E10/E1	45330	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\_431786.

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# Medicines & Healthcare products Regulatory Agency





# REPORT

## PASSAGE HISTORY:

Mixed infection passage: (E7/D1)	A/Hong Kong/2671/2019 wild type virus @10 <sup>-3</sup> x A/Puerto Rico/8/34 (H1N1) @10 ↓		
1 <sup>st</sup> Antiserum Passage	Inoculum @ 10-3 with antiserum to	HA titre = 80	
(E7/D2)	A/Puerto Rico/8/34 (H1N1)		
	Ļ		
2 <sup>nd</sup> Antiserum Passage	Inoculum @ 10-3 with antiserum to	HA titre = 640	
(E7/D3)	A/Puerto Rico/8/34 (H1N1)		
	$\downarrow$		
3 <sup>rd</sup> Antiserum/	Inoculum @ 10.7 with antiserum to	HA titre = 126	
1st Limit Dilution Passage*	A/Puerto Rico/8/34 (H1N1)		
(E7/D4)	Ţ		
4 <sup>th</sup> Antiserum/	Inoculum @ 10-7 with antiserum to	HA titre = 135	
2nd Limit Dilution Passage*	A/Puerto Rico/8/34 (H1N1)		
(E7/D5)	$\downarrow$		
5 <sup>th</sup> Antiserum/	Inoculum @ 10-7 with antiserum to	HA titre = 320	
3rd Limit Dilution Passage*	A/Puerto Rico/8/34 (H1N1)		
(E7/D6)	$\downarrow$		
4th Limit Dilution Passage	Inoculum @ 10-8	HA titre =538	
(E7/D7)	$\downarrow$		
5th Limit Dilution Passage	Inoculum @ 10-7	HA titre =394	
(E7/D8)	$\downarrow$		
6th Limit Dilution Passage	Inoculum @ 10-6	HA titre =394	
(E7/D9)	$\downarrow$		
Preparation of Seedlot VI-1651 (IVR-208), 10th Passage	Inoculum @ 10-5	Mean HA titre =1302	

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