Medicines & Healthcare products Regulatory Agency



#### Influenza Reagent Influenza Virus Infectious NIB-127 (H3N2) NIBSC code: 21/226 Instructions for use (Version 2.0, Dated 22/09/2021)

## 1. INTENDED USE

Reagent 21/226 is prepared from NIB-127 which was processed in  $250\mu$ l volumes as liquid stock. The derivation and known passage history of NIB-127 (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 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	Oxidising:	No		
Hygroscopic:	No	Irritant:	No		
Flammable:	No	Handling:See	caution, Section 2		
Other (specify):	Live influenza	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 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 NIB-127 (H3N2)

Cumulative number of	Passage numbers at each stage	Lot	Laboratory
passages			
E1-E4	E4	#10042174	Unknown
E5	E4/E1	46220	NIBSC, UK
E10	E4/E1/E5	46420	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\_4362772.

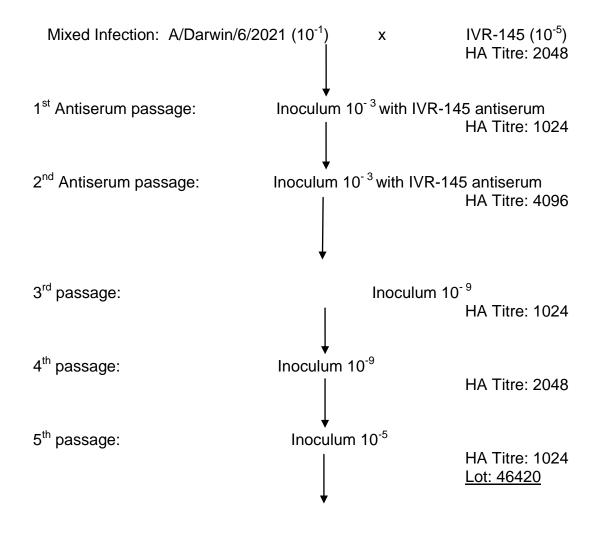
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## Derivation of NIB-127 High Growth Reassortant

Strain: A/Darwin/6/2021 Received from VIDRL: E4, 08/06/2021 Passage undertaken at NIBSC: #46220, E1

Genetic analysis 6:2



Total number of passages since mixed infection= E5

SPF eggs were used for all passages.

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.

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UK Official Medicines Control Laboratory