



**Influenza Reagent  
Influenza Virus Infectious NIB-104  
NIBSC code: 17/194  
Instructions for use  
(Version 2.0, Dated 23/11/2017)**

**1. INTENDED USE**

Reagent 17/194 is prepared from NIB-104 (A/Singapore/INFIMH-16-0019/2016 x IVR-145) (H3N2) which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The derivation and known passage history of NIB-104 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 ampoule contains 250µl (nominal) of infectious influenza virus as allantoic fluid from SPF embryonated hen's eggs.

**5. STORAGE**

Store in the dark at -20°C or below

**Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.**

**6. DIRECTIONS FOR OPENING**

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

**7. USE OF MATERIAL**

Reconstitute the contents of one ampoule of reagent with 250µl of sterile distilled water. Leave for a minimum of 5 minutes before use to allow for complete solution of freeze-dried material. A range of dilutions (e.g. 10<sup>-3</sup> to 10<sup>-5</sup>) should be made in a suitable medium for initial cultivation.

**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](mailto: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](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](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](mailto: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: white powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See 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 and Conditions for the Supply of Materials (available at [http://www.nibsc.org/About\\_Us/Terms\\_and\\_Conditions.aspx](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**

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 0.25g per ampoule
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> No

**Passage history of NIB-104 (post mixed infection)**

Passage	Lot	Laboratory
E1-E6		NIBSC, Hertfordshire, UK
E7	42770	NIBSC, Hertfordshire, 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 on GISAID with the accession number EPI\_ISL\_282213.



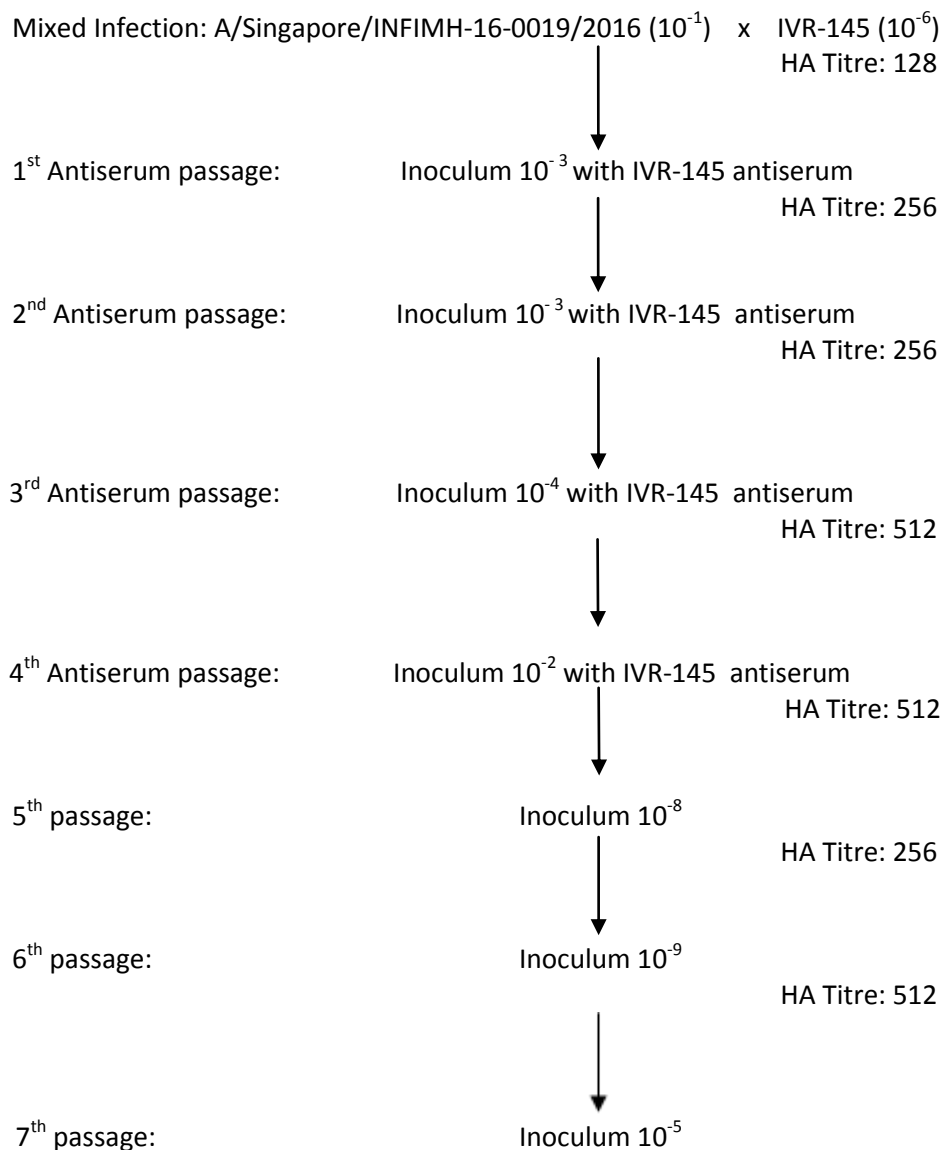
## Derivation of NIB-104

### A/Singapore/INFIMH-16-0019/2016 x IVR-145 (H3N2)-like High Growth Reassortant

Strain: A/Singapore/INFIMH-16-0019/2016 (H3N2)

Received from VIDRL, E5

Passage undertaken at NIBSC #42520, E6





HA Titre: 128

Lot: 42770

Total number of passages since mixed infection= E7  
SPF eggs were used for all passages.

RT-PCR/RFLP analysis indicates that NIB-104 has HA, NA and NS genes from A/Singapore/INFIMH-16-0019/2016 and all remaining genes from IVR-145 (A/PR/8/34), making it a 5:3 reassortant.

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.



**WHO COLLABORATING CENTRE FOR  
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**Influenza Virus Seed Lot**

**Identity Test Report for: National Institute for Biological Standards and Control**

Sample ID No.	NIB-104	Test Code	NA
Seed Lot No.	NA	Date submitted	15/09/2017
Sample name	A/Singapore/INFIMH-16-0019/2016	WHO ID No.	1709685

<b>Test applied</b>	<b>Haemagglutination Inhibition Assay</b>	Assay Date:	26 Sep 2017
Assay performed by:	Tasoula Zakis		

Reference antigen	HI titre with reference antisera							
	A1	A2	A3	A4	A5	A6	A7	A8
A/SWITZERLAND/9715293/2013 A(H3N2)	<b>640</b>	80	160	<80	<20	<20	160	160
A/NEW CALEDONIA/71/2014 A(H3N2)	40	<b>2560</b>	640	<80	<20	<20	640	320
A/HONG KONG/4801/2014 A(H3N2)	40	2560	<b>640</b>	<80	<20	<20	640	320
A/MICHIGAN/45/2015 A(H1N1)pdm	<20	<20	<20	<b>1280</b>	<20	<20	<20	<20
B/BRISBANE/33/2008 (B VIC)	<20	<20	<20	<20	<b>320</b>	<20	<20	<20
B/PHUKET/3073/2013 (B YAM)	<20	<20	<20	<20	<20	<b>640</b>	<20	<20
A/SINGAPORE/INFIMH-16-0019/2016 (WT) A(H3N2)	40	1280	320	<80	<20	<20	<b>640</b>	320
<b>Test antigen</b>								
NIB-104	40	1280	320	<80	<20	<20	640	<b>320</b>
Actual antisera used were raised to:	A1	A/SWITZERLAND/9715293/2013					A(H3N2)	
	A2	A/NEW CALEDONIA/71/2014					A(H3N2)	
	A3	A/HONG KONG/4801/2014					A(H3N2)	
	A4	A/MICHIGAN/45/2015					A(H1N1)pdm	
	A5	B/BRISBANE/33/2008					(B VIC)	
	A6	B/PHUKET/3073/2013					(B YAM)	
	A7	A/SINGAPORE/INFIMH-16-0019/16					(WT) A(H3N2)	
	A8	NIB-104(A/SINGAPORE/INFIMH-16-0019/2016) NIBSC F12/17					Reassortant A(H3N2)	

**Conclusion:** NIB-104 has a HI reactivity pattern that is consistent with the wild-type egg propagated virus A/SINGAPORE/INFIMH-16-0019/16 and therefore passes the One-Way HI test. NIB-104 also passes the Two-Way HI test based on results obtained with antisera produced against the reassortant virus NIB-104 (A8; supplied by NIBSC).

Pass  Fail  Warn



**Ian Barr**  
Deputy Director  
3.10.2017