

Influenza Reagent Influenza virus infectious NIB-50 NIBSC code: 07/358 Instructions for use (Version 1.0, Dated 17/03/2008)

1. INTENDED USE

Reagent 07/358 is prepared from NIB-50 (A/Uruguay/716/2007 (H3N2) x A/PR/8/34 (H1N1)) which was processed for freeze drying in $250\mu l$ volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The known passage history of NIB-50 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 ampoule contains 250µl (nominal) of infectious influenza virus as allantoic fluid from SPF embryonated hen's eggs.

5. STORAGE

Store in the dark at -20C 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.10-3 to 10-5) should be made in a suitable medium for initial cultivation.

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.

REFERENCES

NA

ACKNOWLEDGEMENTS 10.

NA

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**

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/

Derivation of International Units: Ordering standards from NIBSC:

http://www.nibsc.org/standardisation/international_standards.aspx

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

		-11						
Physical and Chemical properties								
Physical appearance:			Corrosive:	No				
White powder								
Stable:	Yes		Oxidising:	No				
Hygroscopic: I	No		Irritant:	No				
Flammable:			Handling:See caution, Section 2					
Other (specify): Live influenza virus								
	Toxicological properties							
Effects of inhalation: Likel			ihood of influer	nza virus infection				
Effects of ingestion: Not		Not e	established, av	oid ingestion				
Effects of skin absorption: Not		Not e	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								

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.

Attached: No	

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: NA

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Passage history of NIB-50 (post mixed infection)

Passage	Lot	Laboratory
E - E4		NIBSC, Hertfordshire, UK
E5	29650	NIBSC, Hertfordshire, UK

WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory



<u>Derivation of NIB-50</u> A/Uruguay/716/2007 (H3N2)-like High Growth Reassortant

Strain: A/Uruguay/716/2007 (H3N2) Received from CDC #2007731384, SpfCKE3 Passage undertaken at NIBSC #29460, SpfCKE4

Mixed Infection: A/Uruguay/716/2007 (10⁻¹) A/PR/8/34 (H1N1)(10⁻⁴) HA Titre: 2560 1st Antiserum passage: Inoculum 10⁻³ with A/PR/8/34 antiserum HA Titre: 2048 2nd Antiserum passage: Inoculum 10⁻³ with A/PR/8/34 antiserum HA Titre: 640 3rd Antiserum passage: Inoculum 10⁻⁶ with A/PR/8/34 antiserum HA Titre: 1280 4th passage: Inoculum 10⁻⁹ HA Titre: 5120 5th passage (seed material) Inoculum 10⁻⁵ HA Titre: 1280 Lot 29650

Total number of passages since mixed infection=E5. SPF eggs were used for all passages.

RT-PCR/RFLP analysis indicates that NIB-50 has HA and NA genes from A/Uruguay/716/2007 and NP, NS, PB1, PB2, PA and M genes from A/PR/8/34 making it a 6:2 reassortant.



The HI data below was provided by the WHO Collaborating Center, NIMR, London, UK. Based on that data they concluded that NIB-50 is similar to wild type A/Uruguay/716/2007(H3N2)

Antigenic analyses of influenza A H3N2 viruses (26/02/08)

			Haemagglutination inhibition titre										
			Post infection ferret sera										
	Viruses	Passage											
		History	1	2	3	4	5	6	7	8	9	10	11
	REFERENCE VIRUSES												
1	A/Wisconsin/67/2005	SpfCk3E3\3	5120	5120	2560	2560	1280	1280	5120	2560	5120	2560	5120
2	A/Nepal/921/2006	E2\2	5120	5120	5120	5120	2560	5120	5120	2560	5120	5120	5120
3	A/Trieste/25c/2007	Mx\2	80	80	80	40	40	<40	160	160	40	160	80
4	A/Sofia/319/2007	E2\2	5120	5120	2560	2560	640	1280	2560	640	5120	2560	5120
5	A/Serres/77/2007	E1\1	5120	5120	2560	5120	2560	1280	2650	1280	5120	2560	5120
6	A/Prague/3/2007	M3, E4\2	5120	5120	2560	2560	1280	1280	2560	640	5120	2560	5120
7	A/Trieste/25E/2007	Mx\2,E1	5120	2560	2560	1280	640	640	2560	640	5120	1280	5120
8	A/Wisconsin/3/2007	Ex\2	5120	5120	2560	2560	2560	1280	2560	2560	5120	5120	5120
9	A/Henan/Jinshui/147/2007	E3\1	5120	5120	2560	2560	640	1280	2560	1280	5120	2560	5120
10	A/Brisbane/10/2007	E2\3	5120	5120	2560	2560	640	1280	2560	1280	5120	2560	5120
11	A/Uruguay/716/2007	Spfck1, E3\1	5120	5120	2560	2560	640	1280	2560	1280	5120	2560	5120
	TEST VIRUSES												
	NIB-50	29650 E5	2560	5120	2560	1280	320	640	1280	640	5120	1280	2560