



Influenza Reagent
Influenza virus infectious IVR-145
NIBSC code: 07/144
Instructions for use
(Version 2.0, Dated 04/04/2008)

1. INTENDED USE

Reagent 07/362 is prepared from IVR-145 (A/Solomon Islands/3/2006 (H1N1) x IVR-6 (H3N2)) which was processed for freeze drying in 250 µl volumes as described by Campbel, PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The known passage history of IVR-145 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 embryonated SPF 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. 10⁻³ to 10⁻⁶) 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

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

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: 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 a 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: NA
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable.
Attached: No

Passage history of IVR-145 (post mixed infection)

Passage level	Lot	Laboratory
E1-E5		CSL, Melbourne, Australia
E6	VI 1498	CSL, Melbourne, Australia
E7	25390	NIBSC, Hertfordshire, UK



Derivation of A/Solomon Islands/3/06-like influenza virus IVR-145 SPF lot VI-1498:

<i>Mixed infection passage:</i>	A/Solomon Islands/3/2006 Wild Type Virus @ 10^{-3} x A/Texas/1/77 (H3N2) IVR-6 @ 10^{-3}	HA titre ≥ 1470
	↓	
<i>1st Antiserum Passage</i>	Inoculum @ 10^{-3} with A/Texas/1/77 antiserum	HA titre 113
	↓	
<i>2nd Antiserum Passage</i>	Inoculum @ 10^{-3} with A/Texas/1/77 antiserum	HA titre 269
	↓	
<i>1st Clone passage</i>	Inoculum @ 10^{-8}	HA titre ≥ 1749
	↓	
<i>2nd Clone passage</i>	Inoculum @ 10^{-9}	HA titre ≥ 1689
	↓	
<i>3rd Clone passage</i>	Inoculum @ 10^{-10}	HA titre ≥ 1689
	↓	
<i>Preparation of SPF Lot VI-1498</i>	Inoculum @ 10^{-5}	mean HA titre = 1717

Total number of passages since this virus was received from an approved laboratory = 7

TESTING OF INFLUENZA VIRUS SPF LOT VI-1498:

Routine testing on SPF lot VI-1498 has been performed as follows:

LIMS Id. 06008761

<i>Sterility</i> Pending (satisfactory at 9 days)	QA Test Code 2572
<i>Mycoplasma</i> Pending	QA Test Code 2703
<i>Haemagglutinin Identity</i> Pending	QA Test Code 0050
<i>EM Appearance</i> Appearance: Pending	QA Test Code 0072
<i>Neuraminidase Identity</i> Pending	QA Test Code 0051
<i>Egg Infectivity</i> Pending	QA Test Code 0052

CONCLUSION:
Pending.

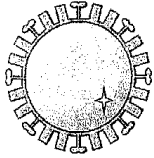
Prepared by:
Peter Schoofs
Manager
Influenza Development, R&D
CSL Limited

Friday, 15 December 2006

Phone: +61 3 9389 1911

CSL Limited A.C.N. 051 588 348
45 Poplar Road Parkville Victoria 3052 Australia

Fax: +61 3 9389 1434



**WHO COLLABORATING CENTRE FOR
REFERENCE AND RESEARCH ON INFLUENZA
MELBOURNE, AUSTRALIA**



45 Poplar Road, Parkville, Victoria 3052, AUSTRALIA
Tel (03) 9389 1166 Fax (03) 9389 1881 Email WHOFLU@influenzacentre.org
www.influenzacentre.org

INFLUENZA HIGH-YIELD REASSORTANT: IVR-145 A/Solomon Islands/3/2006 (H1N1)

DATE OF DERIVATION REPORT: 18 December 2006.

SOURCE:

The reassortant virus IVR-145 (the 'Reassortant') has been made available to the WHO Collaborating Centre (the 'Centre'), by CSL Limited ACN 051 588 348 ('CSL'), for distribution. It is requested that in any citations the origin of the reassortant should be acknowledged as: CSL Limited, Parkville, Australia.

DERIVATION:

The Reassortant was prepared from the A/Solomon Islands/3/2006 virus which was isolated at the Melbourne WHO Collaborating Centre in chicken eggs from healthy disease-free flocks, before being reassorted by CSL Limited. The derivation history of IVR-145 is outlined on the CSL data sheet.

TESTING:

Haemagglutinin Identity.

In reciprocal haemagglutination-inhibition tests conducted at the Centre using reference reagents, SPF Lot VI-1498 (IVR-145) was antigenically equivalent to A/Solomon Islands/3/2006.

Reference antigen	HI titre with reference antisera					
	A1	A2	A3	A4	B	H3
A/NEW CALEDONIA/20/99	1280	320	640	80	<20	<20
A/NOVI SAD/150/2006	640	320	640	80	<20	<20
A/MALAYSIA/100/2006	640	160	1280	160	<20	<20
A/SOLOMON ISLANDS/3/2006	160	40	320	320	<20	<20
B/MALAYSIA/2506/2004	<20	<20	<20	<20	>2560	<20
A/WISCONSIN/67/2005	<20	<20	<20	<20	<20	320
Test antigen						
VI-1498	160	40	320	160	<20	<20
Actual antisera used were raised to:	A1	A/NEW CALEDONIA/20/99 (H1)				
	A2	A/NOVI SAD/150/2006 (H1)				
	A3	A/MALAYSIA/100/2006 (H1)				
	A4	A/SOLOMON ISLANDS/3/2006 (H1)				
	B	B/MALAYSIA/2506/2004				
	H3	A/WISCONSIN/67/2005 (H3)				



Infectivity Titre:
See CSL data sheet

Sterility:
See CSL data sheet.

CAUTION

IVR-145 (VI-1498) is a living biological preparation and should be regarded as potentially hazardous to humans. Appropriate safety procedures should be employed for avoiding exposure and for discarding infectious materials or contaminated equipment. It is the recipient's responsibility for ensuring that it complies with all laws and regulations for the handling and use of the Reassortant

LIABILITY:

1. CSL and the Centre take all reasonable care and skill in preparing the viral isolate and the Reassortant and compiling any information provided herewith and have used reasonable endeavours to ensure that the Reassortant complies with the specification set out in this Information Sheet.
2. However, CSL and the Centre disclaim all warranties, express or implied, concerning the Reassortant including any warranty that it is accurate, complete, safe, merchantable or fit for any purpose such as a basis for preparing vaccines or reagents.
3. The recipient is solely responsible for ensuring that the Reassortant is fit for the use to which (s)he puts same.
4. CSL and the Centre accept no liability whatsoever for any loss, damage or liability which arise as a result of or in connection with the use of the Reassortant including any loss, damage or liability that:
 - arises from CSL's or the Centre's negligence or wilful default; or
 - relates to any product derived from use of the Reassortant; or
 - relates to any results obtained from use of the Reassortant; or
 - results in direct, indirect, special or consequential damages.

Prepared by:

Ian Barr
Deputy Director
Melbourne WHO Influenza Centre