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 Campbell, 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 allantoinic 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-breaker’ 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^{3}) 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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: White powder</td>
<td>Effects of inhalation: Likelihood of influenza virus infection</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Suggested First Aid</td>
</tr>
<tr>
<td>Other (specify): Live influenza virus</td>
<td>Inhalation: Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Ingestion: Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Contact with eyes: Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td></td>
<td>Contact with skin: Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

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_Acceptable_Use.aspx or on
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)

<table>
<thead>
<tr>
<th>Passage level</th>
<th>Lot</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1-E5</td>
<td></td>
<td>CSL, Melbourne, Australia</td>
</tr>
<tr>
<td>E6</td>
<td>VI 1498</td>
<td>CSL, Melbourne, Australia</td>
</tr>
<tr>
<td>E7</td>
<td>25390</td>
<td>NIBSC, Hertfordshire, UK</td>
</tr>
</tbody>
</table>
Derivation of A/Solomon Islands/3/06-like influenza virus IVR-145 SPF lot VI-1498:

Mixed infection passage: A/Solomon Islands/3/2006 Wild Type Virus @ 10^3 x A/Texas/1/77 (H3N2) IVR-6 @ 10^3 HA titre ≥ 1470

1st Antiserum Passage Inoculum @ 10^9 with A/Texas/1/77 antiserum HA titre 113

2nd Antiserum Passage Inoculum @ 10^9 with A/Texas/1/77 antiserum HA titre 269

1st Clone passage Inoculum @ 10^6 HA titre ≥ 1749

2nd Clone passage Inoculum @ 10^6 HA titre ≥ 1899

3rd Clone passage Inoculum @ 10^6 HA titre ≥ 1899

Preparation of SPF Lot VI-1498 Inoculum @ 10^6 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

Sterility QA Test Code 2572
PENDING (satisfactory at 9 days)

Mycoplasma QA Test Code 2703
PENDING

Haemagglutinin Identity QA Test Code 0050
PENDING

EM Appearance QA Test Code 0072
Appearance: Pending

Neuraminidase Identity QA Test Code 0051
PENDING

Egg Infectivity QA Test Code 0052
PENDING

CONCLUSION:
PENDING

Prepared by:
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CSL Limited

Friday, 15 December 2006
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.

<table>
<thead>
<tr>
<th>Reference antigen</th>
<th>A1</th>
<th>A2</th>
<th>A3</th>
<th>A4</th>
<th>B</th>
<th>H3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/NEW CALEDONIA/20/99</td>
<td>1280</td>
<td>320</td>
<td>640</td>
<td>80</td>
<td>&lt;20</td>
<td>&lt;20</td>
</tr>
<tr>
<td>A/NOVI SAD/150/2006</td>
<td>640</td>
<td>320</td>
<td>640</td>
<td>80</td>
<td>&lt;20</td>
<td>&lt;20</td>
</tr>
<tr>
<td>A/MALAYSIA/100/2006</td>
<td>640</td>
<td>160</td>
<td>1280</td>
<td>160</td>
<td>&lt;20</td>
<td>&lt;20</td>
</tr>
<tr>
<td>A/SOLOMON ISLANDS/3/2006</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&gt;2560</td>
<td>&lt;20</td>
</tr>
<tr>
<td>B/MALAYSIA/2506/2004</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>320</td>
</tr>
<tr>
<td>A/WISCONSIN/67/2005</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
<td>&lt;20</td>
</tr>
</tbody>
</table>

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 (V1-1498) 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:

[Signature]

Ian Barr
Deputy Director
Melbourne WHO Influenza Centre