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></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: White powder</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of inhalation:</td>
<td>Likelihood of influenza virus infection</td>
</tr>
<tr>
<td>Effects of ingestion:</td>
<td>Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption:</td>
<td>Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>

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-142 (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 1489</td>
<td>CSL, Melbourne, Australia</td>
</tr>
<tr>
<td>E7</td>
<td>24810</td>
<td>NIBSC, Hertfordshire, UK</td>
</tr>
</tbody>
</table>
CSL Research and Development

REPORT ON THE PREPARATION AND TESTING OF
A/Hiroshima/52/2005 SPF LOT NO VI-1489 (IVR-142)

PREPARATION OF SPF LOT:
Preparation of the SPF lot VI-1489 (IVR-142) was carried out following procedures set out in Standard Operating Procedure RDS0030, and in accordance with the Australian Good Laboratory Practice guidelines. This work was conducted in the Influenza Product Development R&D, DB823, CSL Ltd.
This work is documented on Batch Process Sheets: RDB 0916 Lot 175 and RBD0936 Lot VI-1489

VIRUS ISOLATE FROM WHO-CC
Virus originally obtained from NiID, Tokyo, Japan
A/Hiroshima/52/2005
Passages prior to receipt at WHO-CC E3
Passages undertaken in WHO-CC E1 HA 32 (Turkey cells)

A brief description of the preparation of the SPF lot follows:
Mixed infection: A/Hiroshima/52/2005 Wild Virus @10^{-3} x A/PR/8/34@ 10^{-3}
HA=394
↓
1st Antiserum Passage @ 10^{-3} with A/PR/8/34 Antiserum Lot 4430 HA=43
↓
2nd Antiserum Passage @ 10^{-3} with A/PR/8/34 Antiserum Lot 4430 HA=160
↓
1st Clone @ 10^{-9} HA=355
↓
2nd Clone @ 10^{-7} HA=190
↓
3rd Clone @ 10^{-8} HA=453
↓
Preparation of SPF Lot VI-1489 @ 10^{-5} mean HA>625

Total number of passages since this virus was received from an approved laboratory = 7
TESTING OF SPF LOT VI-1489

Routine testing on SPF lot VI-1489 has been performed as follows:

**LIMS Id. 06004547**

**Sterility QA Test Code 2572**  
Pass

**Mycoplasma QA Test Code 2703**  
Pending

**Haemagglutinin Identity QA Test Code 0050**  
Pending

**EM Appearance QA Test Code 0072**  
Appearance: short and medium filaments, small and medium spheres, kidney shapes, some long filaments and large spheres, some irregular shaped particles.  
Micrograph numbers CM1107-1 to CM1107-8.

**Neuraminidase Identity QA Test Code 0051**  
Pending

**Egg Infectivity QA Test Code 0052**  
Pending

**CONCLUSION:**  
Pending

Prepared by:  
Peter Schoofs  
Manager  
CSL Limited Influenza Development

Phone: +61 3 9389 1585  
CSL Limited A.C.N. 051 588 348  
Fax: +61 3 9381 1913  
45 Poplar Road Parkville Victoria 3052 Australia
INFLUENZA HIGH-YIELD REASSORTANT IVR-142 A/Hiroshima/52/2005 (H3N2)

DATE OF DERIVATION REPORT: 6 March 2006.

SOURCE:
The reassortant virus IVR-142 (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/Hiroshima/52/2005 virus which was isolated at the NIID WHO Collaborating Centre in Tokyo, Japan and passaged 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-142 is attached.

TESTING:

Haemagglutinin Identity.

In reciprocal haemagglutination-inhibition tests conducted at the Centre using reference reagents, SPF Lot VI-1489 (IVR-142) was antigenically equivalent to A/Hiroshima/52/2005.

<table>
<thead>
<tr>
<th>Reference antigen A1</th>
<th>Reference antigen A2</th>
<th>Reference antigen A3</th>
<th>Reference antigen B</th>
<th>Reference antigen H1</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/California/7/2004 (Egg)</td>
<td>320</td>
<td>40</td>
<td>80</td>
<td>&lt;40</td>
</tr>
<tr>
<td>A/Brisbane/3/2005 (Egg)</td>
<td>640</td>
<td>640</td>
<td>320</td>
<td>&lt;40</td>
</tr>
<tr>
<td>A/Hiroshima/52/2005 (Egg)</td>
<td>160</td>
<td>40</td>
<td>640</td>
<td>&lt;40</td>
</tr>
<tr>
<td>B/Malaysia/2506/2005</td>
<td>&lt;40</td>
<td>&lt;40</td>
<td>&lt;40</td>
<td>640</td>
</tr>
<tr>
<td>A/New Caledonia/20/99 H1 (Egg)</td>
<td>&lt;40</td>
<td>&lt;40</td>
<td>&lt;40</td>
<td>160</td>
</tr>
</tbody>
</table>

Test antigen

VI-1489 (IVR 142; A/Hiroshima/52/2005) 160 40 640 <40 <40

A1 A/California/7/2004 (H5)
A2 A/Brisbane/3/2005 (H5)
A3 A/Hiroshima/52/2005 (H3)
B B/Malaysia/2506/2005

Actual antisera used were raised to:

H1 A/New Caledonia/20/99
Infectivity Titre:
Pending

Sterility:
CSL SPF lot VI-1489 has been tested and shown to be free of bacterial contaminants.

CAUTION
IVR-142 (VI-1489) 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 it is put.
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