



**Influenza Reagent**  
**Influenza virus infectious IVR-149**  
**NIBSC code: 07/362**  
**Instructions for use**  
**(Version 2.0, Dated 31/03/2008)**

**1. INTENDED USE**

Reagent 007/362 is prepared from IVR-149 (A/Uruguay/716/2007 (H3N2) x A/PR/8/34 (H1N1) ) 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-149 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<sup>-3</sup> to 10<sup>-6</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 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](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> NA
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> No

**Passage history of IVR-149 (post mixed infection)**

Passage level	Lot	Laboratory
E1-E5		CSL, Melbourne, Australia
E6	VI 1517	CSL, Melbourne, Australia
E7	29820	NIBSC, Hertfordshire, UK



**Research  
and Development**

REPORT ON THE PREPARATION AND TESTING OF:

**Influenza virus Reassortant N<sup>o</sup> IVR-149, SPF LOT N<sup>o</sup> VI-1517  
A/Uruguay/716/2007-like, (H3N2)**

**PREPARATION OF SPF LOT:**

Preparation of SPF influenza virus IVR-149, lot VI-1517 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 Development department, R&D, CSL Limited.

This work was documented on Batch Process Sheets: RDB0914, RDB0939, RDB0913, RDB0916, RDB0917 and RDB0936. All Lot No. 197.

**VIRUS ISOLATE FROM WHO-CC**

Virus was obtained from the WHO Collaborating Centre for Reference & Research on Influenza (WHO-CC).

Strain:	A/Uruguay/716/2007 (Type A, Subtype H3N2)
CDC ID Number:	2007731384
Passages prior to receipt at WHO-CC:	SPFCK1 E3
Passages undertaken in WHO-CC:	E0

**Derivation of A/Uruguay/716/2007:**

<i>Mixed Infection passage:</i>	A/Uruguay/716/2007 (H3N2) 10 <sup>-3</sup> x A/Puerto Rico/8/34(H1N1) @ 10 <sup>-3</sup>	HA Titre ≥ 1470
	↓	
<i>1<sup>st</sup> Antiserum passage:</i>	Inoculum @ 10 <sup>-3</sup> with A/Puerto Rico/8/34 antiserum	HA titre 453
	↓	
<i>2<sup>nd</sup> Antiserum passage:</i>	Inoculum @ 10 <sup>-3</sup> with A/Puerto Rico/8/34 antiserum	HA titre ≥ 1631
	↓	
<i>1<sup>st</sup> Clone passage:</i>	Inoculum @ 10 <sup>-7</sup>	HA titre 0
	↓	
<i>2<sup>nd</sup> Clone passage:</i>	Inoculum @ 10 <sup>-5</sup>	HA titre 905
	↓	
<i>6<sup>th</sup> Passage:</i>	Inoculum @ 10 <sup>-8</sup>	HA titre ≥ 1749
	↓	
<i>Preparation of SPF Lot VI-1517:</i>	Inoculum @ 10 <sup>-5</sup>	mean HA titre ≥ 522

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



**TESTING OF INFLUENZA VIRUS SPF LOT VI-1517:**

Routine testing on SPF lot VI-1517 has been performed as follows:

**LIMS Id. PKV-PR-08001488 (Sample No. 862874)**

<b>Sterility</b> Pending	<b>QA Test Code 2572</b>
<b>Mycoplasma</b> Pending	<b>QA Test Code 2703</b>
<b>Mycoplasma</b> Pending	<b>QA Test Code 2705</b>
<b>Mycoplasma (H-Stain)</b> Pending	<b>QA Test Code 1591</b>
<b>Haemagglutinin Identity</b> Pending	<b>QA Test Code 0050</b>
<b>EM Appearance</b> Pending	<b>QA Test Code 0072</b>
<b>Neuraminidase Identity</b> Pending	<b>QA Test Code 0051</b>
<b>Egg Infectivity</b> Pending	<b>QA Test Code 0052</b>

Analysis by RT-PCR indicates that IVR-148 is a 6:2 reassortant i.e. 6 genes derived from A/Puerto Rico/8/34(H1N1) and 2 genes coding for HA and NA are derived from A/Uruguay/716/2007 (H3N2).

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