Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Influenza Reagent
Influenza Virus Infectious IVR-139 (A/Wellington/1/2004 HGR)
NIBSC code: 04/172
Instructions for use
(Version 2.0, Dated 04/04/2008)

1. INTENDED USE

Reagent 04/172 is prepared from IVR-139 which was processed for freeze drying in 250µl volumes for virus cultivation in any suitable medium.

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

5. STORAGE

Store in the dark at -20ºC
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

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
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

No stability data is available for this mater

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267.
The known passage history of IVR-139 is attached

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: Freezen dried 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 skinntact 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 ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological 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.

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

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: 0.25 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

Derivation of IVR-139

Passage level	Lot	Laboratory
E1-E8		Unknown
E9	VI-1474	CSL Ltd, Parkville, Australia
E10	23765	NIBSC, Hertfordshire, UK

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

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INFLUENZA HIGH-YIELD REASSORTANT IVR-139 A/Wellington/1/2004 (H3N2)

SOURCE:

The reassortant virus IVR-139 (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 all publications relating to this virus the origin should be acknowledged as: CSL Limited, Parkville, Australia.

DERIVATION:

The Reassortant was prepared from the A/Wellington/1/2004 virus which was isolated at the WHO Collaborating Centre and passaged in chicken eggs from a healthy disease-free flock. The derivation history of IVR-139 at CSL is attached.

TESTING:

Haemagglutinin Identity.

In reciprocal haemagglutination-inhibition tests conducted at the Centre using reference reagents and recent isolates IVR-139 and its homologous antiserum was antigenically equivalent to A/Wellington/1/2004.

VIRUS	POST-INFECTION FERRET SERA			
	FUJIAN/411	X-147	WELL/1	IVR-139
A/FUJIAN/411/2002	**320**	640	640	320
X-147(A/WYOMING/3/2003)	1280	**5120**	1280	640
A/WELLINGTON/1/2004	160	1280	**1280**	1280
IVR-139 (A/WELLINGTON/1/2004)	640	2560	2560	**2560**

By sequence analysis of the HA1 region of the haemagglutinin a single amino acid change A196T was noted.

Neuraminidase Identity.

By PCR IVR-139 was demonstrated to contain only N_2-neuraminidase.

Infectivity titre.
CSL storage lot VI-1474 has a measured infectivity titre of $10^{7.5}$ ID_{50}/0.2mL in eggs.

Sterility.
CSL storage lot VI-1474 has been tested and shown to be free of bacterial contaminants.