Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**Influenza Reagent**
**Influenza Virus Infectious NIB-64**
**NIBSC code: 09/280**
**Instructions for use**
**(Version 1.0, Dated 09/04/2010)**

## 1. INTENDED USE

Reagent 09/206 is prepared from NIB-64 (A/Perth/16/2009 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 NIB-64 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 freeze dried allantoic fluid from embryonated SPF hen's eggs.

## 5. STORAGE

Store in the dark at -20$^0$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 $10^{-5}$) should be made in a suitable medium for initial cutivation.

## 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.<br>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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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<br>* 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**.**<br>**Attached:** No |

**Derivation of NIB-64**

| Passage | Lot | Laboratory |
|---|---|---|
| E - E3 | | NIBSC, Hertfordshire, UK |
| E4 | 31860 | NIBSC, Hertfordshire, UK |

# Derivation of NIB-64

## A/Perth/16/2009 (H3N2)-like High Growth Reassortant

Strain: A/Perth/16/2009 (H3N2)
Received from WHO Melbourne # SL/0905018-1, E3
Passage undertaken at NIBSC #31460, E4

Mixed Infection: A/Perth/16/2009 ($10^{-2}$) x A/PR/8/34 ($10^{-5}$)
HA Titre: 2560

↓

1st Antiserum passage: Inoculum $10^{-3}$ with A/PR/8/34 antiserum
HA Titre: 480

↓

2nd Antiserum passage: Inoculum $10^{-7}$ with A/PR/8/34 antiserum
HA Titre: 640

↓

3rd passage: Inoculum $10^{-7}$
HA Titre: 640

↓

4th passage Inoculum $10^{-5}$
HA Titre: 640
Lot 31860

Total number of passages since mixed infection=E4.

SPF eggs were used for all passages.

RT-PCR/RFLP analysis indicates that NIB-64 has HA and NA from A/Perth/16/09 and NP, M PB1, PB2 , NS and PA genes from A/PR/8/34, making it a 6:2 reassortant.

National Institute for Biological Standards and Control,
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The HI data below was provided by the WHO Collaborating Centre, NIMR, London, UK.
Based on that data it is concluded that the HA of NIB-64 is very similar to wild type A/Perth/16/2009

| Viruses | Collection Date | Haemagglutination inhibition titre[1] Post infection ferret sera A/Wis 67/05 F1/06 | A/Bris 10/07 F29/08 | A/Uru 716/07 F26/08 | A/Fin/ 9/08 F12/088 | A/HK 1952/09 F22/09 | A/HK 1985/09 F21/09 | A/Perth 16/09 F25/09 | A/Wis 15/09 F24/09 |
|---|---|---|---|---|---|---|---|---|---|
| ***REFERENCE VIRUSES*** | | | | | | | | | |
| **A/Wisconsin/67/2005** | 31/08/2005 | **2560** | 2560 | 2560 | 1280 | 40 | 40 | < | < |
| **A/Brisbane/10/2007** | 06/02/2007 | 1280 | **1280** | 2560 | 1280 | < | < | < | < |
| **A/Uruguay/716/2007** | 21/06/2007 | 1280 | 1280 | **2560** | 1280 | < | < | < | < |
| **A/Finland/9/2008** | 07/01/2008 | 80 | 640 | 320 | **640** | 80 | 320 | 320 | 80 |
| **A/Hong Kong/1952/2009** | 24/03/2009 | 40 | 320 | 160 | 320 | **80** | 320 | 320 | 80 |
| **A/Hong Kong/1985/2009** | 01/04/2009 | 40 | 160 | 80 | 40 | 80 | **320** | 320 | 80 |
| **A/Perth/16/2009** | 04/07/2009 | < | 40 | 80 | < | 320 | 2560 | **2560** | 320 |
| **A/Wisconsin/15/2009** | 06/07/2009 | < | 80 | 80 | < | 320 | 2560 | 2560 | **320** |
| ***TEST VIRUSES*** | | | | | | | | | |
| NIB-64 (A/Perth/16/2009) | | < | 40 | 40 | < | 320 | 2560 | 2560 | 320 |

1. < = <40