



**Influenza Reagent**  
**Influenza Antigen A/Cambodia/RO405050/2007 (H5N1)**  
**NIBSC code: 08/216**  
**Instructions for use**  
**(Version 5.0, Dated 24/03/2014)**

**1. INTENDED USE**

Influenza antigen reagent 08/216 is prepared for single-radial-diffusion assay of A/Cambodia/RO405050/2007 antigens using an appropriate NIBSC antiserum reagent.

**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**

Antigen reagent 08/216 contains 93µg haemagglutinin/ml.

**4. CONTENTS**

Country of origin of biological material: United Kingdom.  
Antigen reagent 08/216 is prepared from BPL-inactivated, partially purified A/Cambodia/RO405050/2007 virus (NIBRG-88), which was suspended in phosphate buffered saline A containing 1% (w/v) sucrose and processed for freeze drying in 1ml volumes as described by Campbell, P.J., Journal of Biological Standardisation, 1974, 2, 249-267.

**The reagent has been inactivated following validated procedures used to produce human influenza vaccine that is registered in the EU. This inactivated reagent has been shown to be free from residual infectious virus by testing according to the European Pharmacopoeia Compendial Assay (monograph 0158).**

**5. STORAGE**

Unopened ampoules should be store at -20oC but storage of reconstituted reagent is not recommended.

**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.**

For all practical purposes each ampoule contains the same quantity of the substances listed above. Reconstitute the total contents of one ampoule of Reagent in 1ml of distilled water. Allow to stand for a minimum of 5 minutes before use to allow for complete solution of freeze dried material. Antigen reagent 08/216 should be used according to the method described by Wood JM, Schild GC, Newman RW and Seagroatt VA. Journal of Biological Standardisation, 1977, 5, 237-247, with the following modification:

It is recommended that Antigen Reagent 08/216 and

A/Cambodia/RO405050/2007 test antigens should be treated with Zwittergent 3-14 detergent (Calbiochem-Behring, La Jolla, CA, USA) before single-radial-diffusion assay. Antigen Reagent 08/216 should be used to assay A/Cambodia/RO405050/2007 antigens using an NIBSC antiserum Reagent.

**8. STABILITY**

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials. Users of the material wishing to refer to the declared ampoule content for use in quantitative or semi-quantitative assay methods should note that the stated content of the material is based on a small collaborative study involving WHO Essential Regulatory Laboratories (ERLs) or Official Medicines Control Laboratories (OMCLs). Studies of recovery and stability of similar antigen preparations indicate that that recovery after ampouling is likely to be close to quantitative, and that no significant loss of content would be expected during storage over at least a 10 year period.

**9. REFERENCES**

Not applicable

**10. ACKNOWLEDGEMENTS**

This reagent was produced on behalf of the FLUSECURE project with funding from the EU.

**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](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

**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: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains inactivated influenza virus



<b>Toxicological properties</b>	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
<b>Suggested First Aid</b>	
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.
<b>Action on Spillage and Method of Disposal</b>	
Spillage of 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.

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> 0.1g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> No