Influenza Reagent
Influenza antigen B/Phuket/3073/2013 (B Yamagata lineage)
NIBSC code: 21/136
Instructions for use
(Version 2.0, Dated 01/07/2021)

1. INTENDED USE
Influenza antigen reagent 21/136 is prepared for single radial diffusion
diagnosis of B/Phuket/3073/2013 egg derived 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
The estimated potency value of 21/136 is 66 µg HA/ml.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Antigen reagent 21/136 is prepared from formalin inactivated, partially
purified B/Phuket/3073/2013 egg derived virus, which was suspended in
PBSA buffer containing 1% (w/v) sucrose and processed for freeze drying
as described in:

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
Pharmacopeia Compendial Assay (monograph 0158).

5. STORAGE
-20°C
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 with 1 ml of distilled water, allow to stand for a minimum of 5
minutes before use to allow for complete solution of freeze dried material.
Antigen 21/136 should be used according to the method described by
Wood, JM, Schild, GC, Newman RW and Seagrott, VA, journal of
Biological Standardisation, 1977, 5, 237-247, with the following modification:
It is recommended that antigen reagent 21/136 and test B/Phuket/3073/2013
egg derived antigens should be treated with Zwittergent 3-14 detergent
(Calbiochem-Behring, La Jolla, CA, USA) before single single radial diffusion
assay. Suitable incubation conditions are as follows:

450 microlitres of antigen are added to 50 microlitres of 10% (w/v)
Zwittergent detergent and incubated in covered containers for 30 minutes at
room temperature (20-25°C). Dilutions of detergent treated antigens are then
added to wells in single radial diffusion immunoplates and incubated at 20-
25°C.

Reagent 21/136 should be used to assay B/Phuket/3073/2013 egg derived
antigens using an appropriate 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 (OMOLs). 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
N/A

10. ACKNOWLEDGEMENTS
N/A

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>
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<tbody>
<tr>
<td>Physical appearance: White powder Corrosive: No</td>
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<tr>
<td>Stable: Yes Oxidising: No</td>
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<tr>
<td>Hygroscopic: No Irritant: No</td>
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<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
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<tr>
<td>Other (specify): Contains inactivated influenza virus</td>
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<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
<td></td>
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<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
<td></td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
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</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 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 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: 1g |  |
| Toxicity Statement: Non-toxic |  |
| Veterinary certificate or other statement if applicable. Attached: No |  |