Non WHO Reference Material Influenza A (H1N2) Panel NIBSC code: 24/140 Instructions for use (Version 2.0, Dated 29/04/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This reagent is intended for performance monitoring of assays detecting Influenza A H1N2. The reagent consists of 8 members: 7 positive samples (members 1-7) which are intended to give a standard curve followed by a blank sample (8) containing (diluent only).

Results may vary depending on the extraction and amplification instruments or assays used. Therefore, users are advised to verify the reagent's performance on their specific instruments and assays.

To account for potential batch-to-batch variation, users should validate the performance of each new reagent batch before use.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is of bovine origin. The material is certified to be obtained from animals taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE & which has not been fed rations containing ruminant derived protein during that period. 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 reagent.

4. CONTENTS

Country of origin of biological material: United Kingdom.

The Influenza A (H1N2) Panel 24/140-xxx comprises of 8 panel members, each of a 1.0 mL volume, with samples 1-7 positive for heat inactivated Influenza A H1N2, and sample 8 a negative. This reagent is in PBS containing 2% HI FCS.

Strain information: A/Swine/England/045393/2022

5. STORAGE

The Influenza A (H1N2) Panel 24/140-xxx is shipped on dry ice and should be delivered in a frozen state. Upon receipt the panel should be stored at -80°C or below until use. Once thawed, the panel should not be refrozen or aliquoted and should be discarded after use.

Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care

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

NIBSC Confidence in Biological Medicines

should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freezedried material prior to reconstitution

If the packaging is damaged or if the reagent arrives thawed it should be discarded and NIBSC contacted for a replacement.

Thaw and mix thoroughly prior to use. The Influenza A (H1N2) Panel 24/140-xxx is a whole inactivated virus and is ready to use. Once thawed do not refreeze. Any residual reagent should be discarded after use. The reagent is intended for use without further dilution.

Users are encouraged to provide information on the performance of the reagent in their assay(s), by e-mail to diagnostics@nibsc.org.

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. Stability studies are carried out to ensure stated stability of this product.

9. REFERENCES

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10. ACKNOWLEDGEMENTS

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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



Medicines & Healthcare products Regulatory Agency



Physical and Chemical properties				
Physical appearance: Clear liquid		Corrosive:	No	
Stable: Yes		Oxidising:	No	
Hygroscopi No c:		Irritant:	No	
Flammable: No		Handling: S	See caution, Section 2	
Other To be handled as infectious as per label. (specify):				
Toxicological properties				
		established, avoid inhalation		
Effects of ingestion: Not		established, avoid ingestion		
Effects of skin	Not	established	avoid contact with	
absorption:	skin			
Suggested First Aid				
Inhalation: Seek medical advice				
Ingestion: Seek medical advice				
Contact with Wash with copious amounts of water. Seek eyes: medical advice				
Contact with Wash skin:	thoro	ughly with w	rater.	
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				

15. LIABILITY AND LOSS

biological waste.

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: Approx 1-2 g per tube

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No