

Working Standard Winter respiratory panel: RSV A NIBSC code: 20/186 Instructions for use (Version 3.0, Dated 16/06/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

This material is a serially diluted panel intended to be run as a complete panel in molecular assays designed for the detection of Respiratory Syncitial Virus (RSV) A. It must be extracted prior to amplification. Panels contain samples diluted from a high concentration to a low concentration. The material can be used to understand assay sensitivity by end-point analysis.

2. CAUTION

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA.

3. UNITAGE

An arbituary unit has been assigned to this material. The panel is a serial dilution from the highest concentration in Sample 1 to the lowest concentration in Sample 6. Sample 1 contains 1,000,000 units, Sample 2 100,000 units, Sample 3 10,000 units, Sample 4 1,000 units, Sample 5 100 units and Sample 6 10 units. Sample 7 is a negative control and should not give any signal.

4. CONTENTS

Country of origin of biological material: United Kingdom.

This panel comprises 7 samples, each containing 1 mL of sample. Samples 1-6 are a serial dilution of a cultured strain of RSV A (strain A2). All dilutions have been performed in PBS. Sample 7 is a negative PBS sample. Effective inactivation has not been proven with this panel and therefore it should be handled as infectious material.

5. STORAGE

This panel should be stored at -20 °C or below (preferably -70 °C if available) upon receipt and continue to be stored at that temperature until 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 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

This material is intended to be thawed and directly extracted, no further manipulation is required.

8. STABILITY

Reference materials are held at NIBSC within assured, temperaturecontrolled storage facilities. Reference Materials should be stored on receipt as indicated on the label. This material has been demonstrated to be stable when left at +4 $^{\circ}$ C for 24 hrs.

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

Physical and Chemical properties					
Physical appearance:			Corrosive:	No	
Frozen liquid					
Stable:	No		Oxidising:	No	
Hygroscopic:	No		Irritant:	No	
Flammable:	No		Handling:See	e caution, Section 2	
Other (specify):	N/A				
Toxicological properties					
Effects of inhalation:		Not established, avoid inhalation			
Effects of ingestion:		Not	Not established, avoid ingestion		
Effects of skin		Not established, avoid contact with			
absorption:		skin	skin		
Suggested First Aid					
Inhalation: Seek medical advice					
Ingestion:	Ingestion: Seek medical advice				
Contact with	Wash with copious amounts of water. Seek				
eyes: medical advice					

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



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.

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 freezedrying.

Net weight: 1g

Toxicity Statement: Toxicity not assessed Veterinary certificate or other statement if applicable.

Attached: No