



**Working Standard**  
**Winter respiratory panel: SARS CoV2**  
**NIBSC code: 20/190**  
**Instructions for use**  
**(Version 4.0, 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 SARS CoV2. 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 arbitrary 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 SARS CoV2 (Melbourne, Vic1). All dilutions have been performed in PBS. Sample 7 is a negative PBS sample. The cultured material has been inactivated using heat and efficacy has been proven via further culture methods. This material is therefore provided as a non infectious panel.

**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 freeze-dried 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, temperature-controlled 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 °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](mailto: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](mailto: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: Frozen liquid	Corrosive: No
Stable: No	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): N/A	
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
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.
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<b>Action on Spillage and Method of Disposal</b>
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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.
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#### 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
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* 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.
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<b>Net weight:</b> 1g
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<b>Toxicity Statement:</b> Toxicity not assessed
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<b>Veterinary certificate or other statement</b> if applicable.
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<b>Attached:</b> No
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