



Non WHO Reference Material
NIBSC Mpx Clade II NAT Panel
NIBSC code: 22/232-XXX
Instructions for use
(Version 1.0, Dated 16/07/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This panel is intended for performance assessment of NAT assays targeting Mpx Clade II, this panel delivers a comprehensive dilution series (samples 1–9) plus a negative control (sample 10), enabling users to generate a standard curve and evaluate assay sensitivity via end-point analysis.

When evaluated with our in-house NAT assay (Roche MagNA Pure 24 extraction platform with Roche LightCycler 480 II amplification instrument) using PAHO G2R G and WA primer/probe sets, the panel yielded Ct values ranging from 20 to 34. Please note that results may vary depending on the extraction method, amplification platform, or PCR assay employed.

This reagent is intended strictly for research use only. It is not designed for assay calibration or any diagnostic applications.

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 any components of this panel.

4. CONTENTS

Country of origin of biological material: United Kingdom.
This ready-to-use panel includes 10 prepared 1 mL samples, designed for consistent and reliable performance. Samples 1 through 9 feature serial 10-fold dilutions of whole virus Clade IIb Mpx whole virus (B.1.lineage), while Sample 10 serves as a negative control. Each dilution is in Copan Universal Transport Medium (UTM) to ensure optimal sample integrity. The virus has been inactivated using a validated combination of acetic acid and heat treatment, making the panel safe to handle as non-infectious. Ideal for assay design and development, validation and training applications.

5. STORAGE

The panel 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.

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

Thaw and mix thoroughly prior to use. Once thawed the panel should not be refrozen and residual reagent should be discarded after use. The reagent should be used 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.

This reagent has a shelf-life of 4 years.

9. REFERENCES

NA

10. ACKNOWLEDGEMENTS

NA

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: Pink/yellow frozen liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: Unknown
Flammable: No	Handling: See caution, Section 2
Other (specify): -	
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.
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 freeze-drying.
Net weight: Approximately 1 g per panel sample
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No