

Non WHO Reference Material Viral Multiplex Reference NIBSC code: 11-242-xxx Instructions for use (Version 4.0, Dated 28/09/2018)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The reagent is intended for use as a reference in adventitious virus detection assays employing deep sequencing technology.

2. CAUTION

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

This preparation contains material of human and bovine origin. The material has been tested and found to be negative for anti-HIV-1 and -2 and HCV RNA. The material is reactive for HBsAg.

The material contains the following infectious viruses

Adenovirus 2 Adenovirus 41

Human herpesvirus 1

Human herpesvirus 2

Human herpesvirus 3 (VZV)

Human herpesvirus 4 (EBV)

Human herpesvirus 5 (CMV)

Rotavirus A

Astrovirus

Norovirus GI

Norovirus GII

Sapovirus C12

Coronavirus 229E

Coxsackievirus B4 Rhinovirus A39

Parechovirus 3

Influenza A virus H1N1

Influenza A virus H3N2

Influenza B virus

Metapneumovirus A

Parainfluenzavirus 1

Parainfluenzavirus 2

Parainfluenzavirus 3

Parainfluenzavirus 4

Respiratory syncytial virus A2

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 preparation.

Selected viruses have been quantified by in-house qPCR as follows:

Parechovirus 7.07 Log10 genome copies / ml Rotavirus 6.76 Log10 genome copies / ml CMV 4.66 Log10 genome copies / ml

5.07 Log10 IU / ml

EBV 3.88 Log10 genome copies / ml

3.81 Log10 IU / ml

RSVA 3.75 Log10 genome copies / ml

Results for CMV and EBV were calibrated against International Standards 09/162 and 09/260, respectively.

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

4. CONTENTS

Country of origin of biological material: United Kingdom.

5. STORAGE

The frozen liquid preparation should be stored at -70°C until use.

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

The vial should be opened under appropriate containment conditions. Unused material should not be re-frozen.

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.

Long-term stability information is not available for this material.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

Users may use the following article for further information, and are requested to reference this article in any publication using the material:

ET Mee, MD Preston, CS533 study participants, PD Minor and S Schepelmann, Vaccine 2016, doi: 10.1016/j.vaccine.2015.12.020

10. ACKNOWLEDGEMENTS

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

(EC) No 1272/2008: Not applicable or not classified				
Physical and Chemical properties				
Physical appearance: Colourless liquid		Corrosive:	No	
Stable: Yes		Oxidising:	No	
Hygroscopic: No		Irritant:	No	
Flammable: No		Handling:See caution, Section 2		
Other (specify):				
Toxicological properties				
Effects of inhalation: Not		established, avoid inhalation		
Effects of ingestion: Risk		of infection		
Effects of skin absorption: Risk		of infection		
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. Seek medical advice.				
Action on Spillage and Method of Disposal				
Spillage of vial contents sho wetted with an appropriate of disinfectant followed by water Absorbent materials used to biological waste.	lisinfed er.	tant. Rinse are	a with an appropriate	

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: 1.5g
Toxicity Statement: Toxic

Veterinary certificate or other statement if applicable.

Attached: No

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