Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Human Parechovirus Working Reagent for Nucleic Acid Amplification Testing
NIBSC code: 08/322-XXX
Instructions for use
(Version 8.0, Dated 19/07/2023)

This material is a self certified IVD and complies with the requirements of the "EU in vitro diagnostic medical device directive 98/79/EC"

1. INTENDED USE

This product is CE marked for use as an IVD within the UK, EU member states and EEA countries. In all other territories this product can be used for research purposes only.
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The reagent is supplied to professional users, typically hospital laboratories, public health organisations and appropriate research organisations. The NIBSC Parechovirus working control is intended to be used as a run control for routine nucleic acid amplification techniques (NAT) assays. The control should be extracted and amplified alongside unknown samples as part of a continuing quality control programme used to monitor assay performance. The use of re-frozen or diluted product or by non-professional users may lead to inconsistent/erroneous results.

2. CAUTION

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

None of the above
Please complete this section manually by typing over this text.
This preparation contains both infectious Parechovirus 3 which has NOT been inactivated and foetal calf serum.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

There is no unitage assigned to this control. The control should therefore be validated for use as a run control and the expected results determined by the end user for their particular NAT assay. NIBSC have determined that the Ct value of the control is approximately 30 using our in-house assay. However different extraction and amplification instruments and different assays may yield different results. Therefore it is important that each user validates this control using their own instruments and assays. **Due to the slight variation between batches users are advised to re-validate their assays when using a new batch of control**.

This material MUST NOT be used for any calibration purposes at all.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial is encoded 08/322-XXX and contains 1.0ml of control. The control consists of a whole virus preparation of Parechovirus 3 diluted in a buffer comprising 10mM Tris-HCl pH7.4 and 2% foetal calf serum.

5. STORAGE

The control should be delivered in a frozen state and then stored at or below -70°C until use. Should the material arrive in a thawed state it should be discarded and NIBSC contacted for a replacement. Material should be thawed once and not refrozen. Once thawed each vial should be stored between +2°C and +8°C and then be used within five days. After this point the material should be discarded. Users are encouraged to inform NIBSC of the performance of the preparation from reviews of their data monitoring. Any user who has data supporting any deterioration in the characteristics of any reference preparation is encouraged to contact NIBSC.

6. DIRECTIONS FOR OPENING

Screw Cap Vials

7. USE OF MATERIAL

The control should be used directly without further dilution and extracted and amplified alongside samples under test. Best results are achieved when the entire volume of the control is extracted. It is recommended that the control be included in each assay run to monitor assay performance.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. All reference materials should be stored immediately on receipt as indicated on the label. The expiry date of this control is indicated on the label when stored at or below -70 C. To ensure stability, this control will be regularly monitored at NIBSC during its shelf life.

9. REFERENCES

10. ACKNOWLEDGEMENTS

1. This control has been produced as part of an ongoing collaboration between NIBSC/HPA, Professor W Carman and the UK Clinical Virology Network.
2. EC REP: Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

11. FURTHER INFORMATION

To use the free, on-line, real-time data reporting and analysis tool RRS with this control please contact ClinicalVirology@nibsc.hpa.org.uk.

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

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

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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: Liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains infectious Parechovirus 3 and materials of animal origin.	
Toxicological properties	
Effects of inhalation: Parechovirus 3	Avoid inhalation - contains infectious
Effects of ingestion: Parechovirus 3	Avoid ingestion - contains infectious
Effects of skin absorption: skin	Not established, avoid contact with
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: 1.0 gram
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No