Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Clinical Virology Multiplex I: Immunodeficiency panel working reagent for Nucleic Acid Amplification Tests (NAT)
NIBSC code: 15/130-XXX
Instructions for use
(Version 8.0, Dated 17/07/2023)

This material is an 'Annex II List B' 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 Clinical Virology Multiplex (Immunodeficiency panel) 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 amplifed alongside unknown samples as part of a continuing quality control programme used to monitor assay performance. The use of diluted product or by non-professional users may lead to inconsitent/erroneous results. The product is not intended to be used as a calibrator.

2. CAUTION

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

None of the above

The preparation contains a dilution of Parvovirus B19 in human plasma which has been tested and found negative for anti-HIV, HIV RNA, anti-HCV, HCV RNA, HBsAg, HBV DNA and HAV RNA.

This preparation contains the following infectious viruses:
Adenovirus serotype 2 (AdV-2)
BK virus (BKV)
Human Cytomegalovirus (HCMV)
Epstein Barr Virus (EBV)
Human herpes Simplex Virus type 1 (HSV-1)
Human herpes Simplex Virus type 2 (HSV-2)
Human herpes Virus type 6A (HHV-6A)
Human herpes Virus type 6B (HHV-6B)
JC virus (JCV)
Parvo B19 virus (B19)
Varicella Zoster Virus (Type B) (VZV)

All viruses have been pre-diluted in a buffer containing fetal 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

A unitage (International Unit) has been assigned to three of the viral targets in this control when reconstituted in 1.0 ml nuclease-free water:
HCMV - 9.5 x 104 IU/ml (8.7 x 104 - 1.0 x 105 IU/ml)
EBV - 5.8 x 104 IU/ml (4.9 x 104 - 6.7 x 104 IU/ml)
B19 - 2.4 x 104 IU/ml (2.2 x 104 - 2.7 x 104 IU/ml)

These unitages were each derived by testing in three independent assays using an in-house test together with the corresponding primary standard, 1st International Standard for HCMV NIBSC code 09/162, 1st International Standard for EBV NIBSC code 09/260 or Non WHO Reference Material for B19 DNA NIBSC code 99/686. The range is a 95% confidence limit in IU/ml.

There is no unitage assigned to the remaining eight targets (AdV-2, BKV, HHV-6A, HHV-6B, HSV-1, HSV-2, JCV, VZV) in this control. NIBSC have determined that the Ct values of the viral targets are approximately 30 using the Roche Ampliprep extraction platform and our in-house assays with the Roche LightCycler 480. 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 15/130-XXX and contains 1.0 ml of lyophilised control reagent. The control consists of whole virus preparations of AdV-2, BKV, HCMV, EBV, HHV-6A, HHV-6B, HSV-1, HSV-2, JCV, B19 and VZV diluted in a buffer comprising 10 mM Tris-HCl pH 7.4, 2% trehalose and 1 mM EDTA.

5. STORAGE

The control is lyophilised and is stable at a variety of temperatures. The control may be shipped at ambient temperature but on receipt it should be stored in a -20°C freezer until use.

Once reconstituted any excess material not used immediately for extraction can be stored at or below 2-8°C and must be used within seven days. After this point the material should be discarded. The reconstituted material must be transferred to a suitable tube that can be pulse spun prior to use to collect all the contents to the bottom of the tube. If storing reconstituted material frozen, the material should be aliquoted into more than one tube if several extractions are required on separate occasions from one vial of product (stability is only validated for one freeze-thaw cycle).

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

Other - describe below...
Vials have a screw cap and an internal stopper. The cap should be removed by turning anti-clockwise and the stopper removed.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE 1434

The material should be reconstituted with 1.0 ml of deionised, nuclease-free molecular-grade water. The control should then be used directly without further dilution and extracted and amplified alongside samples under test. It is recommended that the control be included in each assay run to monitor assay performance.

If packaging is damaged the products cannot be used.

The Result Reporting System (RRS) has been developed by the National Institute for Biological Standards and Control (NIBSC) for the data monitoring of its serology and NAT quality control (QC) reagents. These include the Quality Control Reagent Unit (QCRU) and Clinical Virology Network (CVN) reagents. The system has been successfully running for serology assays for several years, collecting thousands of data points a year; and more recently for data derived from reagents used in Nucleic Acid-based Technologies (NAT) assays. Users are encourage to sign up here: https://nibsc.org/products/rrs

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.

9. REFERENCES

10. ACKNOWLEDGEMENTS

1. This control has been produced as part of an ongoing collaboration between NIBSC 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

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: white solid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains infectious agents and material of human and animal origin		

Toxicological properties	
Effects of inhalation:	Avoid - contains infectious agents
Effects of ingestion:	Avoid - contains infectious agents
Effects of skin absorption:	Avoid - contains infectious agents

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 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No