Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
2019 novel coronavirus (SARS-CoV-2) Working Reagent for Nucleic Acid Amplification Testing (NAT)
NIBSC code: 20/110-XXX
Instructions for use
(Version 4.0, Dated 20/10/2023)

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.

This material should be used as a PCR run control for assays to detect the presence of the novel coronavirus SARS-CoV-2.

The reagent is supplied to professional users, typically hospital laboratories, public health organisations and appropriate research organisations. The NIBSC SARS-CoV-2 virus 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 and therefore should not be performed.

2. CAUTION

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

This reagent does not contain infectious virus. 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

This control is designed and CE marked specifically to be used as a run control. The results from its use must be determined by the end user for their particular NAT assay as different extraction and amplification instruments and different assays are likely to 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.

The potency of 20/110 relative to the International Standard for SARS-CoV-2 NIBSC code 20/146 is 4.15 Log10 IU/mL with 95% CL of 3.83 – 4.47. However this control MUST NOT be used for any calibration purposes at all.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial is encoded 20/110-XXX and contains 0.5ml of control. The control consists of a series of recombinant virus which together encode the entire genome of SARS-CoV-2 diluted in PBS A.

5. STORAGE

The control should be delivered in a frozen state and then stored at or below -20 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 on the same day. After this point the material should be discarded and a new vial used. 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

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 control should be used directly without further dilution. However the addition of inactivation buffers as per normal laboratory protocols is acceptable. The 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.

The material should be fully thawed and mixed prior to use

Note for users of this material and the Roche Cobas SARS-CoV-2 assay.

The Roche Cobas SARS-CoV-2 assay outputs two results. The first "Target 1" is against a non-structural protein unique to SARS-CoV-2. The second "Target 2" is against the E gene. NIBSC have observed that results from this material for Target 1 are entirely as expected but those against Target 2 may be depressed with respect to "Target 1". This is due to a primer/probe mismatch between this material and the Roche Cobas SARS-CoV-2 assay but in no way diminishes the use of this material in its intended purpose as a PCR run control for assays to detect the presence of the novel coronavirus SARS-CoV-2.

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.

The expiry date of this control is indicated on the label when stored at or below -20 C. To ensure stability, this control will be regularly monitored at NIBSC during its shelf life.

9. REFERENCES

Not applicable.

10. ACKNOWLEDGEMENTS

1. Grateful thanks are given to Drs Giada Mattiuzzo and Emma Bentley for their work in preparing this material.

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Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

CE

2. EC Rep. Advena Ltd. Tower Business Centre, 2nd Floor, 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: Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Not applicable		

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 contents should be taken up with absorbent material wetted with an appropriate virucidal agent. Rinse area with an appropriate virucidal agent followed by water. Absorbent materials used to treat spillage should be treated as biologically hazardous 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: 1.0g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached**: No