Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Nucleic Acid Amplification Techniques (NAT) Panel for SARS-CoV-2
NIBSC code: 20/266-XXX
Instructions for use
(Version 5.0, Dated 03/06/2021)

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.
The NAT Panel for SARS-CoV-2 is intended for use as a verification/ validation panel for users who are either making an in-house amplification assays for SARS-CoV-2 or checking manufacturer claims of detection concerning a pre-made SARS-CoV-2 amplification assay.

This panel is suitable for all NAT assays including RT-PCR and LAMP. Althought a unitage is given to each panel member the panel is NOT to be used for calibration or run-control purposes. This panel must NOT be used to determine the limit of detection of any assay.

2. CAUTION

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

The material is not of human or bovine origin.
The NAT panel for SARS-CoV-02 comprises of 30 members of which 24 are positive for acetic acid and heat inactivated SARS-CoV-2 virus Melbourne strain (BetaCoV/Australia/VIC01/2020). There are six different unitages of SARS-CoV-2.
Two panel members are negative controls and the other four panel members are positive for one of Coronavirus 229E, Coronavirus NL63, Respiratory Syncytial Virus Strain A2 or Influenza virus B (B/Jiangsu/10/2003). These viruses are not inactivated. 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

The unitages of the NAT Panel for SARS-CoV-2 were obtained by parallel analysis of the panel members and the WHO International Standard for SARS-CoV-2 NIBSC code 20/146 when run on a Roche Cobas 6800 analyser running the Roche SARS-CoV-2 assay. The specific unitages of each of the SARS-CoV-2 panel members are given in Table 1. Indicative values from analysis of the NAT Panel in a droplet digital PCR assay are shown in Table 2. NAT panel samples 2, 3, 15 and 22 are also reactive when assayed on the Roche LIAT device using the Roche LIAT SARS-CoV-2 & Influenza A/B nucleic acid test. The other panel members were not tested on this device.

THIS PANEL MUST NOT BE USED FOR CALIBRATION PURPOSES OR USED TO DETERMINE THE LIMIT OF DETECTION OF ANY ASSAY.

4. CONTENTS

Country of origin of biological material: United Kingdom.
The NAT Panel for SARS-CoV-2 comprises of 30 0.5ml samples in Virocult Viral Transport Medium in 2ml Screw capped Sarstedt tubes.

5. STORAGE

The NAT Panel for SARS-CoV-2 is shipped in dry ice and should be stored until use at -20°C. Once thawed the panel should not be refrozen and should be discarded after 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 NAT Panel for SARS-CoV-2 is ready to use either in a direct assay or in an extraction procedure prior to amplification. Once thawed the panel should not be refrozen and should be discarded after use, however the panel may be used multiple times but only on the same day as initial defrosting. The panel must not be stored defrosted for periods of longer than 4 hours.

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.

9. REFERENCES

10. ACKNOWLEDGEMENTS

EC REP Advena Ltd. Tower Business Centre, 2nd Floor, 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

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

CE

Physical and Chemical properties			
Physical appearance: Brown liquid.		Corrosive:	No
Stable:	No	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:	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: 1 gramme
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No

Table 1.

Data obtained by parallel analysis of the NAT panel in the Roche 6800 device running the Roche SARS-CoV-2 assay in parallel with the WHO International Standard for SARS-CoV-2 20/146.

NAT Panel Sample	Pathogen	Nominal Concentration in International Units/ml.
1	Negative control	N/A
2	SARS-CoV-2	3.8×10^5/ml
3	SARS-CoV-2	1.5×10^5/ml
4	SARS-CoV-2	1.3×10^8/ml
5	SARS-CoV-2	3.0×10^7/ml
6	SARS-CoV-2	3.0×10^7/ml
7	SARS-CoV-2	3.0×10^7/ml
8	SARS-CoV-2	4.5×10^6/ml
9	SARS-CoV-2	2.1×10^6/ml
10	SARS-CoV-2	1.3×10^8/ml
11	SARS-CoV-2	4.5×10^6/ml
12	SARS-CoV-2	2.1×10^6/ml
13	Coronavirus 229E	N/A
14	SARS-CoV-2	1.3×10^8/ml
15	SARS-CoV-2	3.8×10^5/ml
16	Coronavirus NL63	N/A
17	SARS-CoV-2	4.5×10^6/ml
18	SARS-CoV-2	3.0×10^7/ml
19	SARS-CoV-2	4.5×10^6/ml
20	SARS-CoV-2	2.1×10^6/ml
21	Influenza B (B/Jiangsu/10/2003)	N/A
22	SARS-CoV-2	1.5×10^5/ml
23	Negative control	N/A
24	SARS-CoV-2	2.1×10^6/ml
25	SARS-CoV-2	1.3×10^8/ml
26	SARS-CoV-2	1.3×10^8/ml
27	SARS-CoV-2	2.1×10^8/ml
28	SARS-CoV-2	4.5×10^6/ml
29	Respiratory Syncytial Virus A	N/A
30	SARS-CoV-2	3.0×10^7/ml

Table 2.

Data obtained by droplet digital PCR as described below.

Sample	Average copies/µl
4, 10, 14, 25 and 26	3.48 x10^7/ml
5, 6, 7, 18 and 30	2.13 x10^7/ml
8, 11, 17, 19 and 28	1.17 x106/ml
9, 12, 20, 24 and 27	3.84 x10^5/ml
2 and 15	4.76 x10^4/ml
3 and 22	1.79 x10^4/ml

Further to extraction using a Roche MagNA Pure 24 device an RT-PCR reaction was performed on Bio-Rad CX-1000 instrument and droplets were read on QX200 Droplet Reader (Bio-Rad) and data were analysed using the Bio-Rad QuantaSoft Analysis Pro Software. A minimum of 10,000 droplets were read for each condition.

These results are indicative and different results may be obtained by different laboratories to NIBSC if using different extraction and amplification devices. These results should not be used for calibration or other purposes e.g. to determin a limit of detection of an assay.

Additional data.

NAT panel samples 2, 3, 15 and 22 are also reactive when assayed on the Roche LIAT device using the Roche LIAT SARS-CoV-2 & Influenza A/B nucleic acid test. The other panel members were not tested on this device.