



CE Marked Material
QCRSARSCoV-2QC1 - Anti-SARS-CoV-2 Quality Control 1
NIBSC code: 20/B764
Instructions for use
(Version 4.0, Dated 29/05/2020)

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 EU member states and EEA countries. In all other territories this product can be used for research purposes only.

SARSCoV-2QC1 is intended for use in the internal laboratory quality control of immunoassays that detect SARS-CoV-2 antibodies. The SARSCoV-2QC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with the SARSCoV-2QC1 can be used to construct quality control charts that can be visually monitored each time the assay is run, to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere¹.

SARSCoV-2QC1 is not intended to be used to compare the sensitivity or for the calibration of assays

2. CAUTION

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

SARSCoV-2QC1 was prepared using a pool of 2 convalescent plasma packs known to be SARS-CoV-2 positive. The reactive material used to prepare SARSCoV-2QC1 was non-reactive for HIV RNA, HCV RNA, anti-HIV, anti-HCV, HBsAg, , anti-HIV 1/2, anti-HTLV I+II and Syphilis using commercial EIA kits. The reactive sera were pooled and then diluted in a pool of defibrinated human plasma donations . These samples were non-reactive for HBsAg, anti-HCV, anti-HIV 1/2, anti-HTLV I+II and Syphilis using commercial EIA kits. Bronidox® was added to a concentration of 0.05% (w/v) as a preservative. 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

Table 1 gives a summary of results obtained for SARSCoV-2QC1 Lot No: 20/B764. These results are intended only as a guide to the approximate levels of reactivity to be expected, and may not be exactly reproduced in other laboratories. In each case, at a minimum, three samples of SARSCoV-2QC1 were tested on three separate occasions. The results are expressed as the ratio of mean optical density or other measurement of the SARS-CoV-2 response of the QC1 sample, to the kit manufacturer's calculated cut-off. Assays that have produced positive results and are validated for use with this reagent have been listed in this table.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF QCRSARSCoV-2QC1 1x7mL Blood tubes
Defibrinated Plasma 1mL
Bronidox® (Sigma-Aldrich) 0.05% (w/v)

5. STORAGE

Reagents are to be kept at 2-8°C upon receipt
• Reagents may be stored at 2-8°C until use by date

- For single use only, reagents should be divided into measured aliquots of one use and stored below –20°C to avoid freeze/thaw cycles. Once thawed use immediately. Do not refreeze
- Ensure all containers are properly sealed to avoid drying out of the reagent
- Avoid microbial contamination of this product as this may alter product performance
- Avoid excessively high temperatures or humidity

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

1. Use of this reagent is to be restricted to trained laboratory staff only
2. Use suitable (latex/nitrile) gloves and eye/skin protection
3. Include reagent as a normal sample in routine work list
4. Allow reagent to reach room temperature before use
5. Plot reagent result on a QC chart to monitor performance

This reagent is ready to use. Do not dilute. Do not use this reagent for any other purposes than specified.

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 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. The system has recently been developed to accept data for Nucleic Acid-based Technologies (NAT) reagents and associated assays.
<https://www.nibsc.org/products/rrs.aspx>

9. REFERENCES

1. Levey, S. and Jennings, E.R. (1950) The use of control charts in clinical laboratories. *Am.J.Clin.Pathol.* 20, 1059-1066.

10. ACKNOWLEDGEMENTS

N/A

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):	
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: 7 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No



Table 1: Results obtained for QCRSARSCoV-2QC1 (Lot Number 20/B764 using the following EIA kits.

EIA KIT	Method Options	Test Cut-Off Ration	
		Mean	SD (n-1)
Kit: Liaison XL SARS-CoV-2 S1/S2 IgG Manufacturer: Diasorin Distributor: Diasorin Catalogue number: 311450 Lot number: 354009 and 354011	Automated Protocol	22.4 (AU/ml)	2.7
Kit: EUROIMMUN Anti-SARS-CoV-2 ELSA IgG Manufacturer: EUROIMMUN Distributor: EUROIMMUN Catalogue number: EI 2606-9601 G Lot number: E200408AO	Standard Protocol	3.4 (OD/CO)	0.3
Kit: Elecsys Anti-SARS-CoV-2 Manufacturer: Roche Distributor: Roche Catalogue number: 9203095190 Lot number: 49481301	Automated Protocol	12.5 (COI)	0.2
Kit: WANTAI SARS-CoV-2 Ab ELSA Manufacturer: WANTAI Distributor: WANTAI Catalogue number: WS-1096 Lot number: NCOA20200401	Standard Protocol	14.5 (OD/CO)	2.8