Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

CE Marked Material
Anti-SARSCoV-2 Verification Panel for Serology Assays
NIBSC code: 20/B770
Instructions for use
(Version 3.0, Dated 16/02/2021)

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

Anti-SARS-CoV-2 Verification Panel for Serology Assays is intended for use as a verification panel to detect claims by manufacturers on the detection of SARS-CoV-2 antibodies. This panel can be used as part of a laboratory's verification process when adpoting a new assay for Anti-SARS-CoV-2.

2. CAUTION

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

Anti-SARS-CoV-2 Verification Panel for Serology Assays is compromised of 37 samples. 23 samples are from convalescent plasma packs known to be Anti-SARS-CoV-2 positve. Also included are 14 plasmapacks known to be Anti-SARS-CoV-2 negative.The reactive material used to prepare Anti-SARS-CoV-2 Verification Panel for Serology Assays 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, anit-HTLV I+II and Syphilis using commercial EIA kits. Bronidox® was added to a concentration of 0.05% (w/v) as a preservative.t 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

Tabels 1-14 gives a summary of results obtained for the Anti-SARS-CoV-2 Verification panel for Serology Assays on 13 commercially available assays and one in-house assay. 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.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use panel of 37 samples
REF Ant-SARS-CoV-2 Verification Panel for Serology Assays 1x7mL Blood tubes
Plasma 0.3 mL
Bronidox® (Sigma-Aldrich) 0.05% (w/v)

5. STORAGE

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

This panel is ready to use. Do not dilute. Do not use this reagent for any other purposes then 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.

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

Physical and Chemical properties			
Physical appearance: Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2

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

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

Table 1. Summary of final product testing using the Liaison SARS-CoV-2 S1/S2 IgG assay.

Panel Number	Result (AU/ml)
1	16.9
2	29.1
3	222
4	142
5	192
6	57,4
7	82.3
8	142
9	168
10	140
11	54.3
12	67.0
13	67.0
14	69.2
15	102
16	71.5
17	94.8
18	102
19	118
20	113
21	103
22	121
23	122
24	<3.80
25	<3.80
26	<3.80
27	<3.80
28	<3.80
29	<3.80
30	<3.80
31	<3.80
32	<3.80
33	<3.80
34	<3.80
35	8.43
36	<3.80
37	<3.80

Table 2. Summary of final product testing using the EUROIMMUN Anti-SARS-CoV2 ELISA IgG assay.

Panel Number	Result (OD/CO)
1	1.7
2	3.2
3	8.5
4	7.9
5	8.5
6	5.8
7	5.7
8	7.1
9	7.9
10	8.0
11	4.6
12	4.9
13	5.1
14	4.8
15	5.7
16	4.2
17	6.1
18	7.6
19	5.8
20	6.2
21	6.6
22	6.7
23	6.5
24	0.09
25	0.08
26	0.39
27	0.08
28	0.07
29	0.06
30	0.27
31	0.1
32	0.11
33	0.11
34	0.09
35	0.07
36	0.07
37	0.12

Table 3. Summary of final product testing using the Roche Elecsys Anti-SARS-CoV-2 assay.

Panel Number	Result (cut-off index)
1	17.2
2	8.8
3	50.7
4	27.5
5	90.5
6	54.9
7	8.9
8	101.3
9	50.1
10	49.9
11	14.2
12	51
13	101.7
14	70.1
15	108
16	4.6
17	26.6
18	82.5
19	58.5
20	141.7
21	108.3
22	132
23	123.3
24	0.02
25	0.08
26	0.07
27	0.07
28	0.07
29	0.07
30	0.08
31	0.07
32	0.07
33	0.07
34	0.08
35	0.07
36	0.07
37	0.07

Table 4. Summary of final product testing using the Abbott Architect SARS-CoV-2 IgG assay.

Panel Number	Result (S/CO)
1	3.7
2	1.4
3	6.5
4	4.2
5	7.2
6	4.2
7	4
8	7.2
9	5.8
10	5.8
11	1.8
12	4.4
13	6.4
14	4.5
15	5.3
16	1.2
17	3.9
18	6.4
19	5.1
20	4.5
21	7
22	5.5
23	5
24	0.02
25	0.05
26	0.12
27	0.01
28	0.05
29	0.01
30	0.16
31	0.01
32	0.03
33	0.04
34	0.01
35	0.01
36	0.04
37	0.03

Table 5. Summary of final product testing using the Siemens SARS-CoV-2 Total Antibody assay.

Panel Number	Result (S/CO)
1	5.4
2	> 10.0
3	> 10.0
4	> 10.0
5	> 10.0
6	> 10.0
7	> 10.0
8	> 10.0
9	> 10.0
10	> 10.0
11	> 10.0
12	> 10.0
13	> 10.0
14	> 10.0
15	> 10.0
16	> 10.0
17	> 10.0
18	> 10.0
19	> 10.0
20	> 10.0
21	> 10.0
22	> 10.0
23	> 10.0
24	0.12
25	0.21
26	0.06
27	0.09
28	0.11
29	0.07
30	0.1
31	0.05
32	0.05
33	0.06
34	0.06
35	0.05
36	0.05
37	0.06

Table 6. Summary of final product testing using the Siemens SARS-CoV-2 IgG assay.

Panel Number	Result (S/CO)
1	0.6
2	0.98
3	> 20.0
4	> 20.0
5	> 20.0
6	12.2
7	8.8
8	> 20.0
9	> 20.0
10	> 20.0
11	4.2
12	4.7
13	5.4
14	5.3
15	6.5
16	1.9
17	12.2
18	> 20.0
19	12.2
20	10.3
21	15.2
22	13.5
23	8.4
24	0
25	0.03
26	0.01
27	0
28	0
29	0
30	0.01
31	0
32	0
33	0
34	0
35	0
36	0
37	0

Table 7. Summary of final product testing using the DiaPro COVID-19 IgG assay.

Panel Number	Result (S/CO)
1	8.1
2	10.5
3	11.1
4	9.4
5	11.3
6	7
7	4.2
8	11.2
9	11.3
10	11.1
11	3.9
12	7.3
13	9.6
14	8.3
15	10.1
16	8
17	9.6
18	11.1
19	10.1
20	8.9
21	10.7
22	9.4
23	10.2
24	0.13
25	0.19
26	0.51
27	0.26
28	0.1
29	0.27
30	0.24
31	0.45
32	0.41
33	0.2
34	0.91
35	0.25
36	0.54
37	0.2

Table 8. Summary of final product testing using the DiaSorin SARS-CoV-2 IgM.

Panel Number	Result (INDEX)
1	0.4
2	0.1
3	4.1
4	5
5	1.9
6	6.2
7	1
8	0.5
9	1.9
10	1.8
11	0.3
12	0.3
13	1
14	0.7
15	15.5
16	0.5
17	0.8
18	18.9
19	10.4
20	1.2
21	11.6
22	7.7
23	35.5
24	0.06
25	0.09
26	0.08
27	0.05
28	0.05
29	0.07
30	0.07
31	0.06
32	0.04
33	0.07
34	0.06
35	0.05
36	0.04
37	0.06

Table 9. Summary of final product testing using the Fortress COVID-19 IgM.

Panel Number	Result (OD/CO)
1	0.4
2	0.2
3	7.6
4	9.9
5	14.7
6	26.7
7	3.2
8	0.8
9	6.5
10	6.6
11	0.5
12	0.9
13	2.9
14	2.0
15	32.0
16	0.2
17	2.9
18	31.2
19	6.0
20	6.9
21	17.8
22	29.4
23	32.7
24	0.05
25	0.05
26	0.15
27	0.15
28	0.05
29	0.25
30	0.03
31	0.04
32	0.04
33	0.05
34	0.03
35	0.03
36	2.8
37	0.04

Table 10. Summary of final product testing using the DiaPro COVID-19 IgM.

Panel Number	Result (S/CO)
1	1.4
2	1.1
3	1.4
4	2.6
5	3.4
6	1.1
7	0.6
8	3
9	2
10	2.3
11	0.7
12	1.2
13	1.1
14	1.1
15	2.2
16	0.8
17	1.1
18	1.6
19	1.7
20	0.9
21	1.5
22	1.6
23	2.3
24	0.08
25	0.19
26	0.2
27	0.13
28	0.21
29	0.13
30	0.2
31	0.08
32	0.1
33	0.16
34	0.21
35	0.16
36	0.26
37	0.35

Table 11. Summary of final product testing using the EUROIMMUN Anti-SARS-CoV-2 NCP ELISA (IgG)

Panel Number	Result (OD/CO)
1	2.7
2	2.1
3	6.2
4	3.7
5	5.8
6	3.1
7	2.9
8	5
9	5.6
10	5.5
11	1.4
12	3.4
13	4.3
14	3.3
15	3.9
16	2.4
17	3.1
18	4.9
19	5.1
20	3.3
21	4.9
22	3.5
23	3.4
24	0.05
25	0.1
26	0.17
27	0.03
28	0.03
29	0.02
30	0.15
31	0.09
32	0.04
33	0.08
34	0.18
35	0.05
36	0.2
37	0.06

Table 12. Summary of final product testing using the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA)

Panel Number	Result (OD/CO)
1	3.4
2	2.2
3	9.2
4	9.7
5	8.9
6	2.7
7	5.0
8	4.9
9	5.6
10	5.7
11	9.7
12	3.0
13	5.7
14	6.3
15	5.6
16	2.9
17	2.9
18	7.7
19	2.8
20	4.8
21	4.2
22	9.4
23	5.5
24	0.23
25	0.34
26	1.46
27	0.33
28	0.11
29	0.13
30	0.73
31	0.49
32	0.25
33	0.13
34	0.3
35	0.08
36	0.1
37	1.39

Table 13. Summary of final product testing using the PHE Colindale Anti-SARS-CoV-2 ELISA in-house

Panel Number	Result (S/CO)
1	11.4
2	13.8
3	95.4
4	81.7
5	100.3
6	40.5
7	55.3
8	77.5
9	92.3
10	92.7
11	33.2
12	33
13	38.4
14	35.5
15	54.5
16	33.4
17	55.3
18	78.7
19	47.4
20	63.1
21	67.6
22	68.8
23	71.4
24	1.04
25	1.16
26	1.07
27	0.53
28	0.96
29	1.35
30	1.35
31	1.23
32	1
33	1.36
34	1.36
35	1.04
36	1.23
37	2.01

Table 14. Summary of final product testing using the Fortress COVID-19 Total Antibody assay

Panel Number	Result (OD/CO)
1	10.1
2	20.2
3	21.2
4	21.4
5	21.5
6	21.1
7	21.0
8	21.5
9	21.6
10	20.9
11	21.1
12	21.2
13	21.4
14	21.2
15	21.2
16	21.1
17	20.4
18	21.1
19	14.9
20	20.9
21	21.1
22	21.2
23	21.3
24	2.5
25	0.03
26	0.02
27	0.17
28	0.02
29	0.03
30	0.03
31	0.09
32	0.02
33	0.03
34	0.03
35	0.03
36	0.03
37	0.03

Table 15. Summary of final product testing using the Ortho COVID-19 IgG Antibody assay

Panel Number	Result (OD/CO)
1	2.05
2	3.37
3	11.07
4	9.08
5	10.07
6	6.19
7	7.58
8	9.25
9	9.17
10	9.12
11	5.75
12	6.68
13	7.07
14	6.00
15	6.73
16	4.59
17	8.28
18	9.49
19	8.02
20	8.23
21	8.32
22	8.18
23	7.38
24	0.00
25	0.01
26	0.01
27	0.01
28	0.01
29	0.00
30	0.07
31	0.00
32	0.00
33	0.01
34	0.00
35	0.00
36	0.00
37	0.01