RapidFor SARS-CoV-2 Rapid Antigen Test

Analytical specificity Report

(Microbial interference and Cross reactivity)

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Analytical specificity (Microbial interference and cross reactivity)

Basis: RapidFor SARS-CoV-2 Rapid Antigen Test analytical specificity (microbial interference and cross reactivity) report

Overview

RapidFor SARS-CoV-2 Rapid Antigen Test produced by Vitrosens Biyoteknoloji Ltd. Şti. is expected to detect the SARS-CoV-2 antigen. There may be microbes similar to the coronavirus in normal human specimens, and these microbes may cause cross reactivity or microbial interference and lead to false test results. Therefore, it is necessary to study some microbes similar to the coronavirus and observe the influence of these microbes on the test results. Since the kit is expected to detect two specimen types of nasopharyngeal swab and oropharyngeal swab, and the equivalence of the two specimen matrices has been studied, the analytical specificity study is only conducted on nasopharyngeal swab specimens.

Research objective

Study the following microbes:

1. Viruses similar in classification to the coronavirus;
2. Microbe that can produce clinical symptoms similar to the coronavirus after infection;
3. A variety of microbial flora in normal human respiratory tract;

Observe the influence of these microbes on the test results.

Test kit device

Three lots of the RapidFor SARS-CoV-2 Rapid Antigen Test

Lot 1: S0221041602

Lot 2: S0221041701

Lot 3: S0221041801

Variability assessment

To assess any potential inter-lot variability of the device, prepared samples of each potential cross- reactant were tested on three device lots used. Three operators, Operators 1, 2, and 3, tested and recorded the result of the test independent of the other. Each operator tests study device results from asingle lot on one instrument.

Randomization

The prepared samples were assigned a Sample ID by the researchers responsible for preparing the samples. People who prepared samples were not participating in sample testing. Using Excel, a sequential randomization algorithm was applied to assign the prepared samples to an arbitrary study Sample Number to ensure that selection of the sample for testing with the device is randomized. Threeoperators, Operators 1, 2, and 3, who were responsible for testing and reporting, were blinded to and had no knowledge of the potential cross-reactant being tested, of the objective of the study, nor of theexpected results of the study device. They were only able to observe the randomized and arbitrarily assigned sample number information.

Acceptable standard

1. Negative nasopharyngeal swab specimens with microorganisms and viruses were tested by the kit, the results should be all negative without false positives.
2. Positive nasopharyngeal swab specimens with microorganisms, viruses, and SARS-CoV-2 (2x LoD, 3×LoD, 10 x LoD) were tested by the kit, the results should be all positive without false negatives.

Specimens

1. The SARS-CoV-2 virus cell culture titer was determined by $TCID_{50}$/mL analysis, and the cell culture unit (copies/mL), it was supplied frozen at a concentration of 5×10^6 $TCID_{50}$/mL and 2.0×10^7 copies/mL. The SARS-CoV-2 was first inactivated with Beta-Propiolactone (BPL) at room temperature for 24 hours, and then 37°C water bath 2 hours for secondary inactivation.
2. Total 315 clinical nasopharyngeal swabs that have been confirmed negative for COVID-19 by RT-PCR were collected from health donors and these swabs were randomly numbered.

Organisms and Viruses

The organisms and viruses evaluated in this study were purchased from the Department of Microbiology, Acıbadem University the concentration of these organisms and viruses are shown in the table 1.

Table 1: Microbial samples and corresponding concentrations

No.	Organism/virus	Conc. Tested on Device
1	Staphylococcus aureus	3.0×10^6 CFU/mL
2	Streptococcus pyogenes	1.6×10^6 CFU/mL
3	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL
4	Mumps virus	3.2×10^5 $TCID_{50}$/mL
5	Mycoplasma pneumoniae	1.3×10^7 CFU/mL
6	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL
7	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL
8	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL
9	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL
10	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL
11	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL
12	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL
13	Epstein-Barr virus	1.0×10^7 copies/mL
14	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL
15	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL
16	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL
17	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL
18	*Streptococcus pneumoniae*	1.8×10^6 CFU/mL
19	*Candida albicans*	1.3×10^6 CFU/mL
20	Chlamydia pneumoniae	1.0×10^5 CFU/mL
21	Bordetella pertussis	5.8×10^6 CFU/mL
22	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL
23	*Legionella pneumophila*	2.0×10^6 CFU/mL
24	*Haemophilus influenzae*	2.7×10^6 CFU/mL
25	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL
26	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL
27	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL
28	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL
29	Staphylococcus epidermidis	1.2×10^7 CFU/mL
30	Adenovirus Type 3	$1.0\text{x}10^5$ $TCID_{50}$/mL
31	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL
32	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL
33	Pneumocystis jirovecii	10^6 CFU/mL In-silico (protein blast)
34	*Mycobacterium tuberculosis*	10^6 CFU/mL In-silico (protein blast)
35	Human coronavirus HKU1	10^6 $TCID_{50}$/mL In-silico (protein blast)
36	SARS-coronavirus	2.5×10^5 PFU/mL
37	Human para-flu virus type-1	$1.0\text{x}10^5$ $TCID_{50}$/mL
38	Human para-flu virus type-2	$1.0\text{x}10^5$ $TCID_{50}$/mL
39	Human para-flu virus type-3	$1.0\text{x}10^5$ $TCID_{50}$/mL

40	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL
41	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL
42	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL
43	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL
44	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL
45	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL
46	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL
47	Bordetella parapertussia	$1.0x10^5$ CFU/mL
48	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	8.9×10^5 TCID50/mL

Due to lack of availability, wet testing for pneumocystis jirovecii, mycobacterium tuberculosis and human coronavirus HKU1 was not performed. To evaluate the degree of protein sequence homology,Basic Local Alignment Search Tool for in-silico analysis was used in this study.

The sequence similarity between human coronavirus HKU1 and SARS-CoV-2 virus nucleocapsid protein is 36.74%, homology is low, but the possibility of cross-reactivity cannot be ruled out.

No significant sequence similarity to the SARS-CoV-2 virus nucleocapsid protein was found in pneumocystis jirovecii and mycobacterium tuberculosis, so there was no cross-reactivity.

Testing Sample Preparation

Organisms and viruses without inactivated SARS-CoV-2 virus

Pipette up and down 10 times to make each sample homogeneous before transferring to each swab. 50uL each sample was added to negative nasopharyngeal swabs. The person who prepared sampleswas not involved in sample testing. All samples were randomly labelled.

Table 2: Microbial samples and corresponding concentrations on the swab with amount added for each sample and used extraction solution volume with tested concentration on device.

No.	Organism/Virus	Conc. on the swab	Amount added for each sample (µL)	Vol. of extraction sol. (µL)	Conc. Tested on device	Swab sample no.
1	Staphylococcus aureus	3.0×10^{7} CFU/mL	50	450	3.0×10^{6} CFU/mL	VS21356
2	Streptococcus pyogenes	1.6×10^{7} CFU/mL	50	450	1.6×10^{6} CFU/mL	VS21357
3	Measles Virus, Edmonston	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21358
4	Mumps virus	3.2×10^{6} $TCID_{50}$/mL	50	450	3.2×10^{5} $TCID_{50}$/mL	VS21359
5	Mycoplasma pneumoniae	1.3×10^{8} CFU/mL	50	450	1.3×10^{7} CFU/mL	VS21360
6	Human Metapneumovirus (hMPV)	2.4×10^{6} $TCID_{50}$/mL	50	450	2.4×10^{5} $TCID_{50}$/mL	VS21361
7	Human coronavirus OC43	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21362
8	Human coronavirus 229E	2.5×10^{6} $TCID_{50}$/mL	50	450	2.5×10^{5} $TCID_{50}$/mL	VS21363
9	Influenza B (Victoria strain)	1.5×10^{6} $TCID_{50}$/mL	50	450	1.5×10^{5} $TCID_{50}$/mL	VS21364
10	Influenza B (Y strain)	2.0×10^{6} $TCID_{50}$/mL	50	450	2.0×10^{5} $TCID_{50}$/mL	VS21365
11	Influenza A (H1N1, 2009)	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21366
12	Influenza A (H3N2)	2.0×10^{6} $TCID_{50}$/mL	50	450	2.0×10^{5} $TCID_{50}$/mL	VS21367
13	Epstein-Barr virus	1.0×10^{8} copies/mL	50	450	1.0×10^{7} copies/mL	VS21368
14	Enterovirus 70	3.1×10^{6} $TCID_{50}$/mL	50	450	3.1×10^{5} $TCID_{50}$/mL	VS21369
15	Human Rhinovirus B70	1.0×10^{6} $TCID_{50}$/mL	50	450	1.0×10^{5} $TCID_{50}$/mL	VS21370
16	Respiratory syncytial virus A	1.2×10^{6} $TCID_{50}$/mL	50	450	1.2×10^{5} $TCID_{50}$/mL	VS21371
17	Respiratory syncytial virus B	2.4×10^{6} $TCID_{50}$/mL	50	450	2.4×10^{5} $TCID_{50}$/mL	VS21372
18	*Streptococcus pneumoniae*	1.8×10^{7} CFU/mL	50	450	1.8×10^{6} CFU/mL	VS21373
19	*Candida albicans*	1.3×10^{7} CFU/mL	50	450	1.3×10^{6} CFU/mL	VS21374
20	Chlamydia pneumoniae	1.0×10^{6} CFU/mL	50	450	1.0×10^{5} CFU/mL	VS21375
21	Bordetella pertussis	5.8×10^{7} CFU/mL	50	450	5.8×10^{6} CFU/mL	VS21376
22	Human coronavirus NL63	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21377
23	*Legionella pneumophila*	2.0×10^{7} CFU/mL	50	450	2.0×10^{6} CFU/mL	VS21378

24	*Haemophilus influenzae*	2.7×10^{7} CFU/mL	50	450	2.7×10^{6} CFU/mL	VS21379
25	Parainfluenza virus 1	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21380
26	Parainfluenza virus 2	4.3×10^{6} $TCID_{50}$/mL	50	450	4.3×10^{5} $TCID_{50}$/mL	VS21381
27	Parainfluenza virus 3	1.6×10^{6} $TCID_{50}$/mL	50	450	1.6×10^{5} $TCID_{50}$/mL	VS21382
28	Parainfluenza virus 4	1.3×10^{6} $TCID_{50}$/mL	50	450	1.3×10^{5} $TCID_{50}$/mL	VS21383
29	Staphylococcus epidermidis	1.2×10^{8} CFU/mL	50	450	1.2×10^{7} CFU/mL	VS21384
30	Adenovirus Type 3	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21385
31	Adenovirus Type 5	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21386
32	Adenovirus Type 7	1.8×10^{6} $TCID_{50}$/mL	50	450	1.8×10^{5} $TCID_{50}$/mL	VS21387
33	SARS-coronavirus	2.5×10^{6} PFU/mL	50	450	2.5×10^{5} PFU/mL	VS21388
34	Human para flu virus type-1	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21389
35	Human para flu virus type-2	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21390
36	Human para flu virus type-3	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21391
37	Human para flu virus type-4	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21392
38	Paramyxovirus parotitis	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21393
39	Avian influenza virus (H7N9)	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21394
40	Avian influenza virus (H5N1)	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21395
41	Human Rhinovirus type 1	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21396
42	Human Rhinovirus type 14	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21397
43	Enterovirus CA16	$1.0\text{x}10^{6}$ $TCID_{50}$/mL	50	450	$1.0\text{x}10^{5}$ $TCID_{50}$/mL	VS21398
44	Bordetella parapertussia	$1.0\text{x}10^{6}$ CFU/mL	50	450	$1.0\text{x}10^{5}$ CFU/mL	VS21399
45	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	8.9×10^{6} $TCID_{50}$/mL	50	450	8.9×10^{5} $TCID_{50}$/mL	VS21400

Organisms and viruses with 2xLoD, 3xLoD, 10x LoD concentration of inactivated SARS-CoV-2 virus

1) SARS-CoV-2 virus was diluted with extraction solution to obtain concentration of 2×LoD, 3xLoD and 10xLoD according to the following table.

Original concentration of SARS-CoV-2 virus: 5.0×10^6 TCID50/mL		
Final concentration of SARS-CoV-2 virus (TCID50/mL)	2019-nCoV virus volume (μL)	Final volume (mL)
4.0×10^4(for 2x LoD)	5.0×10^6TCID$_{50}$/mL: 0.008	1
6.0×10^4(for 3x LoD)	5.0×10^6TCID$_{50}$/mL: 0.012	1
20.0×10^4(for 10x LoD)	5.0×10^6TCID$_{50}$/mL: 0.04	1

Original concentration of SARS-CoV-2 virus: 2.0×10^7copies/mL		
Final concentration of SARS-CoV-2 **virus (copies/mL)**	2019-nCoV virus volume (μL)	Final volume (mL)
2.0×10^6(for 2x LoD)	2.0×10^7copies/mL: 0.05	1
3.0×10^6(for 3x LoD)	2.0×10^7copies/mL: 0.075	1
1.0×10^7(for 10x LoD)	2.0×10^7copies/mL: 0.25	1

2) Pipette up and down 10 times to make each sample homogeneous before transferring to each swab. Prepare each organism and virus according to the table 3. The person who prepared samples was not involved in sample testing. All samples were randomly labelled.

Table 3: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (2xLoD) TCID50/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	**Organism**	**Conc. on the swab**	**Amount Added for each sample (μL)**	**Inactivated SARS-CoV-2 (2xLoD) virus added foreach sample(μL)**	**Vol. of Extraction Sol. (μL)**	**Conc. Tested on Device**	**Swab Sample No.**
46	Staphylococcus aureus	3.0×10^7 CFU/mL	50	25	425	3.0×10^6 CFU/mL	VS21401
47	Streptococcus pyogenes	1.6×10^7 CFU/mL	50	25	425	1.6×10^5 CFU/mL	VS21402

48	Measles Virus, Edmonston	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21403
49	Mumps virus	3.2×10^6 $TCID_{50}$/mL	50	25	425	3.2×10^5 $TCID_{50}$/mL	VS21404
50	Mycoplasma pneumoniae	1.3×10^8 CFU/mL	50	25	425	1.3×10^7 CFU/mL	VS21405
51	Human Metapneumovirus (hMPV)	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21406
52	Human coronavirus OC43	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21407
53	Human coronavirus 229E	2.5×10^6 $TCID_{50}$/mL	50	25	425	2.5×10^5 $TCID_{50}$/mL	VS21408
54	Influenza B (Victoria strain)	1.5×10^6 $TCID_{50}$/mL	50	25	425	1.5×10^5 $TCID_{50}$/mL	VS21409
55	Influenza B (Y strain)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21410
56	Influenza A (H1N1, 2009)	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21411
57	Influenza A (H3N2)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21412
58	Epstein-Barr virus	1.0×10^8 copies/mL	50	25	425	1.0×10^7 copies/mL	VS21413
59	Enterovirus 70	3.1×10^6 $TCID_{50}$/mL	50	25	425	3.1×10^5 $TCID_{50}$/mL	VS21414
60	Human Rhinovirus B70	1.0×10^6 $TCID_{50}$/mL	50	25	425	1.0×10^5 $TCID_{50}$/mL	VS21415
61	Respiratory syncytial virus A	1.2×10^6 $TCID_{50}$/mL	50	25	425	1.2×10^5 $TCID_{50}$/mL	VS21416
62	Respiratory syncytial virus B	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21417
63	*Streptococcus pneumoniae*	1.8×10^7 CFU/mL	50	25	425	1.8×10^6 CFU/mL	VS21418
64	*Candida albicans*	1.3×10^7 CFU/mL	50	25	425	1.3×10^6 CFU/mL	VS21419
65	Chlamydia pneumoniae	1.0×10^6 CFU/mL	50	25	425	1.0×10^5 CFU/mL	VS21420
66	Bordetella pertussis	5.8×10^7 CFU/mL	50	25	425	5.8×10^6 CFU/mL	VS21421
67	Human coronavirus NL63	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21422
68	*Legionella pneumophila*	2.0×10^7 CFU/mL	50	25	425	2.0×10^6 CFU/mL	VS21423
69	*Haemophilus influenzae*	2.7×10^7 CFU/mL	50	25	425	2.7×10^6 CFU/mL	VS21424

70	Parainfluenza virus 1	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21425
71	Parainfluenza virus 2	4.3×10^6 $TCID_{50}$/mL	50	25	425	4.3×10^5 $TCID_{50}$/mL	VS21426
72	Parainfluenza virus 3	1.6×10^6 $TCID_{50}$/mL	50	25	425	1.6×10^5 $TCID_{50}$/mL	VS21427
73	Parainfluenza virus 4	1.3×10^6 $TCID_{50}$/mL	50	25	425	1.3×10^5 $TCID_{50}$/mL	VS21428
74	Staphylococcus epidermidis	1.2×10^8 CFU/mL	50	25	425	1.2×10^7 CFU/mL	VS21429
75	Adenovirus Type 5	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21430
76	Adenovirus Type 7	1.8×10^6 TCID50/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21431
77	SARS-coronavirus	2.5×10^6 PFU/mL	50	25	425	2.5×10^5 PFU/mL	VS21432
78	(MERS-CoV)	8.9×10^6 $TCID_{50}$/mL	50	25	425	8.9×10^5 $TCID_{50}$/mL	VS21433
79	Adenovirus Type 3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21434
80	Human para flu virus type-1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21435
81	Human para flu virus type-2	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21436
82	Human para-flu virus type-3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21437
83	Human para-flu virus type-4	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21438
84	Paramyxovirus parotitis	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21439
85	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21440
86	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21441
87	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21442
88	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21443
89	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21444
90	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21445

Table 4: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (3xLoD) TCID50/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	Organism	Conc. on the swab	Amount Added for each sample (µL)	Inactivated SARS-CoV-2 (3xLoD) virus added foreach sample(µL)	Vol. of Extraction Sol. (µL)	Conc. Tested on Device	Swab Sample No.
91	Staphylococcus aureus	3.0×10^{7} CFU/mL	50	25	425	3.0×10^{6} CFU/mL	VS21446
92	Streptococcus pyogenes	1.6×10^{7} CFU/mL	50	25	425	1.6×10^{5} CFU/mL	VS21447
93	Measles Virus, Edmonston	1.8×10^{6} TCID50/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21448
94	Mumps virus	3.2×10^{6} TCID50/mL	50	25	425	3.2×10^{5} $TCID_{50}$/mL	VS21449
95	Mycoplasma pneumoniae	1.3×10^{8} CFU/mL	50	25	425	1.3×10^{7} CFU/mL	VS21450
96	Human Metapneumovirus (hMPV)	2.4×10^{6} TCID50/mL	50	25	425	2.4×10^{5} $TCID_{50}$/mL	VS21451
97	Human coronavirus OC43	1.8×10^{6} TCID50/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21452
98	Human coronavirus 229E	2.5×10^{6} TCID50/mL	50	25	425	2.5×10^{5} $TCID_{50}$/mL	VS21453
99	Influenza B (Victoria strain)	1.5×10^{6} $TCID_{50}$/mL	50	25	425	1.5×10^{5} $TCID_{50}$/mL	VS21454
100	Influenza B (Y strain)	2.0×10^{6} $TCID_{50}$/mL	50	25	425	2.0×10^{5} $TCID_{50}$/mL	VS21455
101	Influenza A (H1N1, 2009)	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21456
102	Influenza A (H3N2)	2.0×10^{6} $TCID_{50}$/mL	50	25	425	2.0×10^{5} $TCID_{50}$/mL	VS21457
103	Epstein-Barr virus	1.0×10^{8} copies/mL	50	25	425	1.0×10^{7} copies/mL	VS21458
104	Enterovirus 70	3.1×10^{6} $TCID_{50}$/mL	50	25	425	3.1×10^{5} $TCID_{50}$/mL	VS21459
105	Human Rhinovirus B70	1.0×10^{6} $TCID_{50}$/mL	50	25	425	1.0×10^{5} $TCID_{50}$/mL	VS21460
106	Respiratory syncytial virus A	1.2×10^{6} $TCID_{50}$/mL	50	25	425	1.2×10^{5} $TCID_{50}$/mL	VS21461
107	Respiratory syncytial	2.4×10^{6}	50	25	425	2.4×10^{5}	VS21462

	virus B	$TCID_{50}$/mL				$TCID_{50}$/mL	
108	*Streptococcus pneumoniae*	1.8×10^{7} CFU/mL	50	25	425	1.8×10^{6} CFU/mL	VS21463
109	*Candida albicans*	1.3×10^{7} CFU/mL	50	25	425	1.3×10^{6} CFU/mL	VS21464
110	Chlamydia pneumoniae	1.0×10^{6} CFU/mL	50	25	425	1.0×10^{5} CFU/mL	VS21465
111	Bordetella pertussis	5.8×10^{7} CFU/mL	50	25	425	5.8×10^{6} CFU/mL	VS21466
112	Human coronavirus NL63	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21467
113	*Legionella pneumophila*	2.0×10^{7} CFU/mL	50	25	425	2.0×10^{6} CFU/mL	VS21468
114	*Haemophilus influenzae*	2.7×10^{7} CFU/mL	50	25	425	2.7×10^{6} CFU/mL	VS21469
115	Parainfluenza virus 1	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21470
116	Parainfluenza virus 2	4.3×10^{6} $TCID_{50}$/mL	50	25	425	4.3×10^{5} $TCID_{50}$/mL	VS21471
117	Parainfluenza virus 3	1.6×10^{6} $TCID_{50}$/mL	50	25	425	1.6×10^{5} $TCID_{50}$/mL	VS21472
118	Parainfluenza virus 4	1.3×10^{6} $TCID_{50}$/mL	50	25	425	1.3×10^{5} $TCID_{50}$/mL	VS21473
119	Staphylococcus epidermidis	1.2×10^{8} CFU/mL	50	25	425	1.2×10^{7} CFU/mL	VS21474
120	Adenovirus Type 5	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21475
121	Adenovirus Type 7	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21476
122	SARS-coronavirus	2.5×10^{6} PFU/mL	50	25	425	2.5×10^{5} PFU/mL	VS21477
123	(MERS-CoV)	8.9×10^{6} $TCID_{50}$/mL	50	25	425	8.9×10^{5} $TCID_{50}$/mL	VS21478
124	Adenovirus Type 3	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21479
125	Human para flu virus type-1	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21480
126	Human para flu virus type-2	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21481
127	Human para-flu virus type-3	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21482
128	Human para-flu virus type-4	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21483
129	Paramyxovirus parotitis	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21484

130	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21485
131	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21486
132	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21487
133	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21488
134	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21489
135	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21490

Table 5: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (10xLoD) TCID50/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	**Organism**	**Conc. on the swab**	**Amount Added for each sample (µL)**	**Inactivated SARS-CoV-2 (10xLoD) virus added for each sample(µL)**	**Vol. of Extraction Sol. (µL)**	**Conc. Tested on Device**	**Swab Sample No.**
136	Staphylococcus aureus	3.0×10^7 CFU/mL	50	25	425	3.0×10^6 CFU/mL	VS21491
137	Streptococcus pyogenes	1.6×10^7 CFU/mL	50	25	425	1.6×10^5 CFU/mL	VS21492
138	Measles Virus, Edmonston	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21493
139	Mumps virus	3.2×10^6 $TCID_{50}$/mL	50	25	425	3.2×10^5 $TCID_{50}$/mL	VS21494
140	Mycoplasma pneumoniae	1.3×10^8 CFU/mL	50	25	425	1.3×10^7 CFU/mL	VS21495
141	Human Metapneumovirus (hMPV)	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21496
142	Human coronavirus OC43	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21497
143	Human coronavirus 229E	2.5×10^6 $TCID_{50}$/mL	50	25	425	2.5×10^5 $TCID_{50}$/mL	VS21498
144	Influenza B (Victoria strain)	1.5×10^6 $TCID_{50}$/mL	50	25	425	1.5×10^5 $TCID_{50}$/mL	VS21499
145	Influenza B (Y strain)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21500

146	Influenza A (H1N1, 2009)	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21501
147	Influenza A (H3N2)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21502
148	Epstein-Barr virus	1.0×10^8 copies/mL	50	25	425	1.0×10^7 copies/mL	VS21503
149	Enterovirus 70	3.1×10^6 $TCID_{50}$/mL	50	25	425	3.1×10^5 $TCID_{50}$/mL	VS21504
150	Human Rhinovirus B70	1.0×10^6 $TCID_{50}$/mL	50	25	425	1.0×10^5 $TCID_{50}$/mL	VS21505
151	Respiratory syncytial virus A	1.2×10^6 $TCID_{50}$/mL	50	25	425	1.2×10^5 $TCID_{50}$/mL	VS21506
152	Respiratory syncytial virus B	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21507
153	*Streptococcus pneumoniae*	1.8×10^7 CFU/mL	50	25	425	1.8×10^6 CFU/mL	VS21508
154	*Candida albicans*	1.3×10^7 CFU/mL	50	25	425	1.3×10^6 CFU/mL	VS21509
155	Chlamydia pneumoniae	1.0×10^6 CFU/mL	50	25	425	1.0×10^5 CFU/mL	VS21510
156	Bordetella pertussis	5.8×10^7 CFU/mL	50	25	425	5.8×10^6 CFU/mL	VS21511
157	Human coronavirus NL63	1.8×10^6 TCID50/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21512
158	*Legionella pneumophila*	2.0×10^7 CFU/mL	50	25	425	2.0×10^6 CFU/mL	VS21513
159	*Haemophilus influenzae*	2.7×10^7 CFU/mL	50	25	425	2.7×10^6 CFU/mL	VS21514
160	Parainfluenza virus 1	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21515
161	Parainfluenza virus 2	4.3×10^6 $TCID_{50}$/mL	50	25	425	4.3×10^5 $TCID_{50}$/mL	VS21516
162	Parainfluenza virus 3	1.6×10^6 $TCID_{50}$/mL	50	25	425	1.6×10^5 $TCID_{50}$/mL	VS21517
163	Parainfluenza virus 4	1.3×10^6 $TCID_{50}$/mL	50	25	425	1.3×10^5 $TCID_{50}$/mL	VS21518
164	Staphylococcus epidermidis	1.2×10^8 CFU/mL	50	25	425	1.2×10^7 CFU/mL	VS21519
165	Adenovirus Type 5	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21520
166	Adenovirus Type 7	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21521
167	SARS-coronavirus	2.5×10^6 PFU/mL	50	25	425	2.5×10^5 PFU/mL	VS21522

168	(MERS-CoV)	8.9×10^6 $TCID_{50}$/mL	50	25	425	8.9×10^5 $TCID_{50}$/mL	VS21523
169	Adenovirus Type 3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21524
170	Human para flu virus type-1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21525
171	Human para flu virus type-2	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21526
172	Human para-flu virus type-3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21527
173	Human para-flu virus type-4	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21528
174	Paramyxovirus parotitis	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21529
175	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21530
176	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21531
177	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21532
178	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21533
179	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21534
180	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21535

Table 6: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (2xLoD) cell copies/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	**Organism**	**Conc. on the swab**	**Amount Added for each sample (µL)**	**Inactivated SARS-CoV-2 (2xLoD) virus added for each sample(µL)**	**Vol. of Extraction Sol. (µL)**	**Conc. Tested on Device**	**Swab Sample No.**
181	Staphylococcus aureus	3.0×10^7 CFU/mL	50	25	425	3.0×10^6 CFU/mL	VS21536
182	Streptococcus pyogenes	1.6×10^7 CFU/mL	50	25	425	1.6×10^5 CFU/mL	VS21537
183	Measles Virus, Edmonston	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21538

184	Mumps virus	3.2×10^6 $TCID_{50}$/mL	50	25	425	3.2×10^5 $TCID_{50}$/mL	VS21539
185	Mycoplasma pneumoniae	1.3×10^8 CFU/mL	50	25	425	1.3×10^7 CFU/mL	VS21540
186	Human Metapneumovirus (hMPV)	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21541
187	Human coronavirus OC43	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21542
188	Human coronavirus 229E	2.5×10^6 $TCID_{50}$/mL	50	25	425	2.5×10^5 $TCID_{50}$/mL	VS21543
189	Influenza B (Victoria strain)	1.5×10^6 $TCID_{50}$/mL	50	25	425	1.5×10^5 $TCID_{50}$/mL	VS21544
190	Influenza B (Y strain)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21545
191	Influenza A (H1N1, 2009)	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21546
192	Influenza A (H3N2)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21547
193	Epstein-Barr virus	1.0×10^8 copies/mL	50	25	425	1.0×10^7 copies/mL	VS21548
194	Enterovirus 70	3.1×10^6 $TCID_{50}$/mL	50	25	425	3.1×10^5 $TCID_{50}$/mL	VS21549
195	Human Rhinovirus B70	1.0×10^6 TCID50/mL	50	25	425	1.0×10^5 $TCID_{50}$/mL	VS21550
196	Respiratory syncytial virus A	1.2×10^6 TCID50/mL	50	25	425	1.2×10^5 $TCID_{50}$/mL	VS21551
197	Respiratory syncytial virus B	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21552
198	*Streptococcus pneumoniae*	1.8×10^7 CFU/mL	50	25	425	1.8×10^6 CFU/mL	VS21553
199	*Candida albicans*	1.3×10^7 CFU/mL	50	25	425	1.3×10^6 CFU/mL	VS21554
200	Chlamydia pneumoniae	1.0×10^6 CFU/mL	50	25	425	1.0×10^5 CFU/mL	VS21555
201	Bordetella pertussis	5.8×10^7 CFU/mL	50	25	425	5.8×10^6 CFU/mL	VS21556
202	Human coronavirus NL63	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21557
203	*Legionella pneumophila*	2.0×10^7 CFU/mL	50	25	425	2.0×10^6 CFU/mL	VS21558
204	*Haemophilus influenzae*	2.7×10^7 CFU/mL	50	25	425	2.7×10^6 CFU/mL	VS21559

205	Parainfluenza virus 1	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21560
206	Parainfluenza virus 2	4.3×10^6 $TCID_{50}$/mL	50	25	425	4.3×10^5 $TCID_{50}$/mL	VS21561
207	Parainfluenza virus 3	1.6×10^6 $TCID_{50}$/mL	50	25	425	1.6×10^5 $TCID_{50}$/mL	VS21562
208	Parainfluenza virus 4	1.3×10^6 $TCID_{50}$/mL	50	25	425	1.3×10^5 $TCID_{50}$/mL	VS21563
209	Staphylococcus epidermidis	1.2×10^8 CFU/mL	50	25	425	1.2×10^7 CFU/mL	VS21564
210	Adenovirus Type 5	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21565
211	Adenovirus Type 7	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21566
212	SARS-coronavirus	2.5×10^6 PFU/mL	50	25	425	2.5×10^5 PFU/mL	VS21567
213	(MERS-CoV)	8.9×10^6 $TCID_{50}$/mL	50	25	425	8.9×10^5 $TCID_{50}$/mL	VS21568
214	Adenovirus Type 3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21569
215	Human para flu virus type-1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21570
216	Human para flu virus type-2	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21571
217	Human para-flu virus type-3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21572
218	Human para-flu virus type-4	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21573
219	Paramyxovirus parotitis	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21574
220	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21575
221	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21576
222	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21577
223	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21578
224	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21579
225	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21580

Table 7: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (3xLoD) cell copies/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	Organism	Conc. on the swab	Amount Added for each sample (µL)	Inactivated SARS-CoV-2 (3xLoD) virus added for each sample(µL)	Vol. of Extraction Sol. (µL)	Conc. Tested on Device	Swab Sample No.
226	Staphylococcus aureus	3.0×10^{7} CFU/mL	50	25	425	3.0×10^{6} CFU/mL	VS21581
227	Streptococcus pyogenes	1.6×10^{7} CFU/mL	50	25	425	1.6×10^{5} CFU/mL	VS21582
228	Measles Virus, Edmonston	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21583
229	Mumps virus	3.2×10^{6} $TCID_{50}$/mL	50	25	425	3.2×10^{5} $TCID_{50}$/mL	VS21584
230	Mycoplasma pneumoniae	1.3×10^{8} CFU/mL	50	25	425	1.3×10^{7} CFU/mL	VS21585
231	Human Metapneumovirus (hMPV)	2.4×10^{6} $TCID_{50}$/mL	50	25	425	2.4×10^{5} $TCID_{50}$/mL	VS21586
232	Human coronavirus OC43	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21587
233	Human coronavirus 229E	2.5×10^{6} $TCID_{50}$/mL	50	25	425	2.5×10^{5} $TCID_{50}$/mL	VS21588
234	Influenza B (Victoria strain)	1.5×10^{6} $TCID_{50}$/mL	50	25	425	1.5×10^{5} $TCID_{50}$/mL	VS21589
235	Influenza B (Y strain)	2.0×10^{6} $TCID_{50}$/mL	50	25	425	2.0×10^{5} $TCID_{50}$/mL	VS21590
236	Influenza A (H1N1, 2009)	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21591
237	Influenza A (H3N2)	2.0×10^{6} $TCID_{50}$/mL	50	25	425	2.0×10^{5} $TCID_{50}$/mL	VS21592
238	Epstein-Barr virus	1.0×10^{8} copies/mL	50	25	425	1.0×10^{7} copies/mL	VS21593
239	Enterovirus 70	3.1×10^{6} $TCID_{50}$/mL	50	25	425	3.1×10^{5} $TCID_{50}$/mL	VS21594
240	Human Rhinovirus B70	1.0×10^{6} $TCID_{50}$/mL	50	25	425	1.0×10^{5} $TCID_{50}$/mL	VS21595
241	Respiratory syncytial virus A	1.2×10^{6} $TCID_{50}$/mL	50	25	425	1.2×10^{5} $TCID_{50}$/mL	VS21596
242	Respiratory syncytial	2.4×10^{6}	50	25	425	2.4×10^{5}	VS21597

	virus B	$TCID_{50}$/mL				$TCID_{50}$/mL	
243	*Streptococcus pneumoniae*	1.8×10^{7} CFU/mL	50	25	425	1.8×10^{6} CFU/mL	VS21598
244	*Candida albicans*	1.3×10^{7} CFU/mL	50	25	425	1.3×10^{6} CFU/mL	VS21599
245	Chlamydia pneumoniae	1.0×10^{6} CFU/mL	50	25	425	1.0×10^{5} CFU/mL	VS21600
246	Bordetella pertussis	5.8×10^{7} CFU/mL	50	25	425	5.8×10^{6} CFU/mL	VS21601
247	Human coronavirus NL63	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21602
248	*Legionella pneumophila*	2.0×10^{7} CFU/mL	50	25	425	2.0×10^{6} CFU/mL	VS21603
249	*Haemophilus influenzae*	2.7×10^{7} CFU/mL	50	25	425	2.7×10^{6} CFU/mL	VS21604
250	Parainfluenza virus 1	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21605
251	Parainfluenza virus 2	4.3×10^{6} $TCID_{50}$/mL	50	25	425	4.3×10^{5} $TCID_{50}$/mL	VS21606
252	Parainfluenza virus 3	1.6×10^{6} $TCID_{50}$/mL	50	25	425	1.6×10^{5} $TCID_{50}$/mL	VS21607
253	Parainfluenza virus 4	1.3×10^{6} $TCID_{50}$/mL	50	25	425	1.3×10^{5} $TCID_{50}$/mL	VS21608
254	Staphylococcus epidermidis	1.2×10^{8} CFU/mL	50	25	425	1.2×10^{7} CFU/mL	VS21609
255	Adenovirus Type 5	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21610
256	Adenovirus Type 7	1.8×10^{6} $TCID_{50}$/mL	50	25	425	1.8×10^{5} $TCID_{50}$/mL	VS21611
257	SARS-coronavirus	2.5×10^{6} PFU/mL	50	25	425	2.5×10^{5} PFU/mL	VS21612
258	(MERS-CoV)	8.9×10^{6} $TCID_{50}$/mL	50	25	425	8.9×10^{5} $TCID_{50}$/mL	VS21613
259	Adenovirus Type 3	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21614
260	Human para flu virus type-1	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21615
261	Human para flu virus type-2	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21616
262	Human para-flu virus type-3	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21617
263	Human para-flu virus type-4	$1.0x10^{6}$ $TCID_{50}$/mL	50	25	425	$1.0x10^{5}$ $TCID_{50}$/mL	VS21618

264	Paramyxovirus parotitis	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21619
265	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21620
266	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21621
267	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21622
268	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21623
269	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21624
270	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21625

Table 8: Organism and their concentration with added volume and volume of inactivated SARS-CoV-2 virus (10xLoD) cell copies/mL, volume of extraction solution and concentration tested on device with swab sample.

No.	**Organism**	**Conc. on the swab**	**Amount Added for each sample (µL)**	**Inactivated SARS-CoV-2 (10xLoD) virus added for each sample(µL)**	**Vol. of Extraction Sol. (µL)**	**Conc. Tested on Device**	**Swab Sample No.**
271	Staphylococcus aureus	3.0×10^7 CFU/mL	50	25	425	3.0×10^6 CFU/mL	VS21626
272	Streptococcus pyogenes	1.6×10^7 CFU/mL	50	25	425	1.6×10^5 CFU/mL	VS21627
273	Measles Virus, Edmonston	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21628
274	Mumps virus	3.2×10^6 $TCID_{50}$/mL	50	25	425	3.2×10^5 $TCID_{50}$/mL	VS21629
275	Mycoplasma pneumoniae	1.3×10^8 CFU/mL	50	25	425	1.3×10^7 CFU/mL	VS21630
276	Human Metapneumovirus (hMPV)	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21631
277	Human coronavirus OC43	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21632
278	Human coronavirus 229E	2.5×10^6 $TCID_{50}$/mL	50	25	425	2.5×10^5 $TCID_{50}$/mL	VS21633
279	Influenza B (Victoria strain)	1.5×10^6 $TCID_{50}$/mL	50	25	425	1.5×10^5 $TCID_{50}$/mL	VS21634

280	Influenza B (Y strain)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21635
281	Influenza A (H1N1, 2009)	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21636
282	Influenza A (H3N2)	2.0×10^6 $TCID_{50}$/mL	50	25	425	2.0×10^5 $TCID_{50}$/mL	VS21637
283	Epstein-Barr virus	1.0×10^8 copies/mL	50	25	425	1.0×10^7 copies/mL	VS21638
284	Enterovirus 70	3.1×10^6 $TCID_{50}$/mL	50	25	425	3.1×10^5 $TCID_{50}$/mL	VS21639
285	Human Rhinovirus B70	1.0×10^6 $TCID_{50}$/mL	50	25	425	1.0×10^5 $TCID_{50}$/mL	VS21640
286	Respiratory syncytial virus A	1.2×10^6 $TCID_{50}$/mL	50	25	425	1.2×10^5 $TCID_{50}$/mL	VS21641
287	Respiratory syncytial virus B	2.4×10^6 $TCID_{50}$/mL	50	25	425	2.4×10^5 $TCID_{50}$/mL	VS21642
288	*Streptococcus pneumoniae*	1.8×10^7 CFU/mL	50	25	425	1.8×10^6 CFU/mL	VS21643
289	*Candida albicans*	1.3×10^7 CFU/mL	50	25	425	1.3×10^6 CFU/mL	VS21644
290	Chlamydia pneumoniae	1.0×10^6 CFU/mL	50	25	425	1.0×10^5 CFU/mL	VS21645
291	Bordetella pertussis	5.8×10^7 CFU/mL	50	25	425	5.8×10^6 CFU/mL	VS21646
292	Human coronavirus NL63	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21647
293	*Legionella pneumophila*	2.0×10^7 CFU/mL	50	25	425	2.0×10^6 CFU/mL	VS21648
294	*Haemophilus influenzae*	2.7×10^7 CFU/mL	50	25	425	2.7×10^6 CFU/mL	VS21649
295	Parainfluenza virus 1	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21650
296	Parainfluenza virus 2	4.3×10^6 $TCID_{50}$/mL	50	25	425	4.3×10^5 $TCID_{50}$/mL	VS21651
297	Parainfluenza virus 3	1.6×10^6 $TCID_{50}$/mL	50	25	425	1.6×10^5 $TCID_{50}$/mL	VS21652
298	Parainfluenza virus 4	1.3×10^6 $TCID_{50}$/mL	50	25	425	1.3×10^5 $TCID_{50}$/mL	VS21653
299	Staphylococcus epidermidis	1.2×10^8 CFU/mL	50	25	425	1.2×10^7 CFU/mL	VS21654
300	Adenovirus Type 5	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21655
301	Adenovirus Type 7	1.8×10^6 $TCID_{50}$/mL	50	25	425	1.8×10^5 $TCID_{50}$/mL	VS21656

302	SARS-coronavirus	2.5×10^6 PFU/mL	50	25	425	2.5×10^5 PFU/mL	VS21657
303	(MERS-CoV)	8.9×10^6 $TCID_{50}$/mL	50	25	425	8.9×10^5 $TCID_{50}$/mL	VS21658
304	Adenovirus Type 3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21659
305	Human para flu virus type-1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21660
306	Human para flu virus type-2	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21661
307	Human para-flu virus type-3	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21662
308	Human para-flu virus type-4	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21663
309	Paramyxovirus parotitis	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21664
310	Avian influenza virus (H7N9)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21665
311	Avian influenza virus (H5N1)	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21666
312	Human Rhinovirus type 1	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21667
313	Human Rhinovirus type 14	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21668
314	Enterovirus CA16	$1.0x10^6$ $TCID_{50}$/mL	50	25	425	$1.0x10^5$ $TCID_{50}$/mL	VS21669
315	Bordetella parapertussia	$1.0x10^6$ CFU/mL	50	25	425	$1.0x10^5$ CFU/mL	VS21670

Testing Procedures

1. Devices were divided into three main groups. These were;
    a. First group was tested for substances with the unspiked inactivated SARS-CoV-2 virus sample.
    b. Second groups were divided into three subgroups for $TCID_{50}$/mL analysis. First subgroup was tested for substances with the spiked inactivated SARS-CoV-2virus for 2xLoD, second subgroup tested for substances with the spiked inactivated SARS-CoV-2 virus for 3xLoD and third subgroup was tested for substances with the spiked inactivated SARS-CoV-2virus for 10xLoD.

c. Third groups were divided into three subgroups for cell copies/mL analysis. First subgroup was tested for substances with the spiked inactivated SARS-CoV-2virus for 2xLoD, second subgroup tested for substances with the spiked inactivated SARS-CoV-2 virus for 3xLoD and third subgroup was tested for substances with the spiked inactivated SARS-CoV-2virus for 10xLoD.

2. Triplicate tests using three different device lots were performed by three operators according to procedures of the IFU.
3. When occurs cross reaction, diluted the sample to verify the no interference concentration.

Results statistics and data analysis

The prepared samples were tested in singlicate on three device lots according to the test procedure in the study device IFU. Researchers applied the randomized and blinded prepared samples to the study devices following the procedures for sample testing in the study device IFU. Except for severe acute respiratory syndrome coronavirus (SARS-CoV), no cross-reactivity/ interference of the Antigen Test was observed with any of the potential cross-reactants when tested at the concentrations listed in tablesbelow.

Cross reactivity - without the inactivated SARS-CoV-2 virus.

No.	Swab Sample No.	Organism/virus	Concentration Tested on Device	Operator 1 Lot 1: S0221041602	Operator 2 Lot 2: S0221041701	Operator 3 Lot 3: S0221041801
1	VS21356	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
2	VS21357	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
3	VS21358	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
4	VS21359	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
5	VS21360	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
6	VS21361	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
7	VS21362	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
8	VS21363	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
9	VS21364	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
10	VS21365	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)

11	VS21366	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
12	VS21367	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
13	VS21368	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
14	VS21369	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
15	VS21370	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
16	VS21371	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
17	VS21372	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
18	VS21373	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
19	VS21374	Candida albicans	1.3×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
20	VS21375	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
21	VS21376	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
22	VS21377	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
23	VS21378	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
24	VS21379	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
25	VS21380	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
26	VS21381	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
27	VS21382	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
28	VS21383	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
29	VS21384	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
30	VS21385	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
31	VS21386	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
32	VS21387	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
33	VS21388	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
34	VS21389	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
35	VS21390	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
36	VS21391	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
37	VS21392	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
38	VS21393	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
39	VS21394	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)

40	VS21395	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
41	VS21396	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
42	VS21397	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
43	VS21398	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
44	VS21399	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)
45	VS21400	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(-/-)	3/3(-/-)	3/3(-/-)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 2×LoD concentration by $TCID_{50/mL}$ analysis

No.	Swab Sample No.	Organism/virus	Concentration Tested on Device	Operator 1 Lot 1: S0221041602	Operator 2 Lot 2: S0221041701	Operator 3 Lot 3: S0221041801
46	VS21401	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
47	VS21402	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
48	VS21403	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
49	VS21404	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
50	VS21405	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
51	VS21406	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
52	VS21407	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
53	VS21408	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
54	VS21409	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
55	VS21410	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
56	VS21411	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
57	VS21412	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
58	VS21413	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
59	VS21414	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
60	VS21415	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
61	VS21416	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
62	VS21417	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
63	VS21418	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

64	VS21419	Candida albicans	1.3×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
65	VS21420	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
66	VS21421	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
67	VS21422	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
68	VS21423	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
69	VS21424	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
70	VS21425	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
71	VS21426	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
72	VS21427	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
73	VS21428	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
74	VS21429	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
75	VS21430	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
76	VS21431	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
77	VS21432	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
78	VS21433	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
79	VS21434	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
80	VS21435	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
81	VS21436	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
82	VS21437	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
83	VS21438	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
84	VS21439	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
85	VS21440	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
86	VS21441	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
87	VS21442	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
88	VS21443	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
89	VS21444	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
90	VS21445	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 3×LoD concentration by $TCID_{50/mL}$ analysis

No.	Swab Sample No.	Organism/virus	Concentration Tested on Device	Operator 1 Lot 1: S0221041602	Operator 2 Lot 2: S0221041701	Operator 3 Lot 3: S0221041801
91	VS21446	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
92	VS21447	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
93	VS21448	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
94	VS21449	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
95	VS21450	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
96	VS21451	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
97	VS21452	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
98	VS21453	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
99	VS21454	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
100	VS21455	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
101	VS21456	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
102	VS21457	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
103	VS21458	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
104	VS21459	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
105	VS21460	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
106	VS21461	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
107	VS21462	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
108	VS21463	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
109	VS21464	Candida albicans	1.3×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
110	VS21465	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
111	VS21466	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
112	VS21467	Human coronavirus NL63	1.8×10^5 TCID50/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
113	VS21468	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
114	VS21469	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
115	VS21470	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

116	VS21471	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
117	VS21472	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
118	VS21473	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
119	VS21474	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
120	VS21475	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
121	VS21476	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
122	VS21477	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
123	VS21478	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
124	VS21479	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
125	VS21480	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
126	VS21481	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
127	VS21482	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
128	VS21483	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
129	VS21484	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
130	VS21485	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
131	VS21486	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
132	VS21487	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
133	VS21488	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
134	VS21489	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
135	VS21490	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 10×LoD concentration by $TCID_{50/mL}$ analysis

No.	**Swab Sample No.**	**Organism/virus**	**Concentration Tested on Device**	**Operator 1 Lot 1: S0221041602**	**Operator 2 Lot 2: S0221041701**	**Operator 3 Lot 3: S0221041801**
136	VS21491	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
137	VS21492	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
138	VS21493	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
139	VS21494	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

140	VS21495	Mycoplasma pneumoniae	1.3×10^{7} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
141	VS21496	Human Metapneumovirus (hMPV)	2.4×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
142	VS21497	Human coronavirus OC43	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
143	VS21498	Human coronavirus 229E	2.5×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
144	VS21499	Influenza B (Victoria strain)	1.5×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
145	VS21500	Influenza B (Y strain)	2.0×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
146	VS21501	Influenza A (H1N1, 2009)	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
147	VS21502	Influenza A (H3N2)	2.0×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
148	VS21503	Epstein-Barr virus	1.0×10^{7} copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
149	VS21504	Enterovirus 70	3.1×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
150	VS21505	Human Rhinovirus B70	1.0×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
151	VS21506	Respiratory syncytial virus A	1.2×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
152	VS21507	Respiratory syncytial virus B	2.4×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
153	VS21508	Streptococcus pneumoniae	1.8×10^{6} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
154	VS21509	Candida albicans	1.3×10^{6} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
155	VS21510	Chlamydia pneumoniae	1.0×10^{5} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
156	VS21511	Bordetella pertussis	5.8×10^{6} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
157	VS21512	Human coronavirus NL63	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
158	VS21513	Legionella pneumophila	2.0×10^{6} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
159	VS21514	Haemophilus influenzae	2.7×10^{6} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
160	VS21515	Parainfluenza virus 1	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
161	VS21516	Parainfluenza virus 2	4.3×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
162	VS21517	Parainfluenza virus 3	1.6×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
163	VS21518	Parainfluenza virus 4	1.3×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
164	VS21519	Staphylococcus epidermidis	1.2×10^{7} CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
165	VS21520	Adenovirus Type 5	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
166	VS21521	Adenovirus Type 7	1.8×10^{5} $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
167	VS21522	SARS-coronavirus	2.5×10^{5} PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
168	VS21523	MERS-CoV	8.9×10^{5}	3/3(+/+)	3/3(+/+)	3/3(+/+)

			$TCID_{50}$/mL			
169	VS21524	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
170	VS21525	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
171	VS21526	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
172	VS21527	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
173	VS21528	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
174	VS21529	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
175	VS21530	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
176	VS21531	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
177	VS21532	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
178	VS21533	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
179	VS21534	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
180	VS21535	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 2×LoD concentration by cell copies/mL study

No.	**Swab Sample No.**	**Organism/virus**	**Concentration Tested on Device**	**Operator 1 Lot 1: S0221041602**	**Operator 2 Lot 2: S0221041701**	**Operator 3 Lot 3: S0221041801**
181	VS21536	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
182	VS21537	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
183	VS21538	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
184	VS21539	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
185	VS21540	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
186	VS21541	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
187	VS21542	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
188	VS21543	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
189	VS21544	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
190	VS21545	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
191	VS21546	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

192	VS21547	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
193	VS21548	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
194	VS21549	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
195	VS21550	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
196	VS21551	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
197	VS21552	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
198	VS21553	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
199	VS21554	Candida albicans	1.3×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
200	VS21555	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
201	VS21556	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
202	VS21557	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
203	VS21558	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
204	VS21559	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
205	VS21560	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
206	VS21561	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
207	VS21562	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
208	VS21563	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
209	VS21564	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
210	VS21565	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
211	VS21566	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
212	VS21567	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
213	VS21568	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
214	VS21569	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
215	VS21570	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
216	VS21571	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
217	VS21572	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
218	VS21573	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
219	VS21574	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
220	VS21575	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

221	VS21576	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
222	VS21577	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
223	VS21578	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
224	VS21579	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
225	VS21580	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 3×LoD concentration by cell copies/mL study

No.	Swab Sample No.	Organism/virus	Concentration Tested on Device	Operator 1 Lot 1: S0221041602	Operator 2 Lot 2: S0221041701	Operator 3 Lot 3: S0221041801
226	VS21581	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
227	VS21582	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
228	VS21583	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
229	VS21584	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
230	VS21585	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
231	VS21586	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
232	VS21587	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
233	VS21588	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
234	VS21589	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
235	VS21590	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
236	VS21591	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
237	VS21592	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
238	VS21593	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
239	VS21594	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
240	VS21595	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
241	VS21596	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
242	VS21597	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
243	VS21598	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

244	VS21599	Candida albicans	1.3×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
245	VS21600	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
246	VS21601	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
247	VS21602	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
248	VS21603	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
249	VS21604	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
250	VS21605	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
251	VS21606	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
252	VS21607	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
253	VS21608	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
254	VS21609	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
255	VS21610	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
256	VS21611	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
257	VS21612	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
258	VS21613	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
259	VS21614	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
260	VS21615	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
261	VS21616	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
262	VS21617	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
263	VS21618	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
264	VS21619	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
265	VS21620	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
266	VS21621	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
267	VS21622	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
268	VS21623	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
269	VS21624	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
270	VS21625	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

Interference - with the inactivated SARS-CoV-2 virus at 10×LoD concentration by cell copies/mL study

No.	Swab Sample No.	Organism/virus	Concentration Tested on Device	Operator 1 Lot 1: S0221041602	Operator 2 Lot 2: S0221041701	Operator 3 Lot 3: S0221041801
271	VS21626	Staphylococcus aureus	3.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
272	VS21627	Streptococcus pyogenes	1.6×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
273	VS21628	Measles Virus, Edmonston	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
274	VS21629	Mumps virus	3.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
275	VS21630	Mycoplasma pneumoniae	1.3×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
276	VS21631	Human Metapneumovirus (hMPV)	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
277	VS21632	Human coronavirus OC43	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
278	VS21633	Human coronavirus 229E	2.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
279	VS21634	Influenza B (Victoria strain)	1.5×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
280	VS21635	Influenza B (Y strain)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
281	VS21636	Influenza A (H1N1, 2009)	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
282	VS21637	Influenza A (H3N2)	2.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
283	VS21638	Epstein-Barr virus	1.0×10^7 copies/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
284	VS21639	Enterovirus 70	3.1×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
285	VS21640	Human Rhinovirus B70	1.0×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
286	VS21641	Respiratory syncytial virus A	1.2×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
287	VS21642	Respiratory syncytial virus B	2.4×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
288	VS21643	Streptococcus pneumoniae	1.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
289	VS21644	Candida albicans	1.3×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
290	VS21645	Chlamydia pneumoniae	1.0×10^5 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
291	VS21646	Bordetella pertussis	5.8×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
292	VS21647	Human coronavirus NL63	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
293	VS21648	Legionella pneumophila	2.0×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
294	VS21649	Haemophilus influenzae	2.7×10^6 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
295	VS21650	Parainfluenza virus 1	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

296	VS21651	Parainfluenza virus 2	4.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
297	VS21652	Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
298	VS21653	Parainfluenza virus 4	1.3×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
299	VS21654	Staphylococcus epidermidis	1.2×10^7 CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
300	VS21655	Adenovirus Type 5	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
301	VS21656	Adenovirus Type 7	1.8×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
302	VS21657	SARS-coronavirus	2.5×10^5 PFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
303	VS21658	MERS-CoV	8.9×10^5 $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
304	VS21659	Adenovirus Type 3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
305	VS21660	Human para-flu virus type-1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
306	VS21661	Human para-flu virus type-2	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
307	VS21662	Human para-flu virus type-3	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
308	VS21663	Human para-flu virus type-4	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
309	VS21664	Paramyxovirus parotitis	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
310	VS21665	Avian influenza virus (H7N9)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
311	VS21666	Avian influenza virus (H5N1)	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
312	VS21667	Human Rhinovirus type 1	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
313	VS21668	Human Rhinovirus type 14	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
314	VS21669	Enterovirus CA16	$1.0x10^5$ $TCID_{50}$/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)
315	VS21670	Bordetella parapertussia	$1.0x10^5$ CFU/mL	3/3(+/+)	3/3(+/+)	3/3(+/+)

Note: "+" indicates a positive result, and "-" indicates a negative result.

A series of limiting dilutions of the inactivated SARS-CoV was performed to determine the highest concentrations at which this virus tested negative on the device. At each dilution, contrived samples were tested in singlicate on three separate device lots according to the test procedure in the study device IFU.

Table 4. Liquid preparation of SARS-CoV

Original concentration of SARS-CoV: 1.0×10^8 PFU/mL			
Virus Original Conc.	volume (μL)	Extraction solution volume (μL)	Final Conc.
1.0×10^8PFU/mL	14	56	2.0×10^7 PFU/mL
1.0×10^8PFU/mL	15	135	1.0×10^7 PFU/mL
1.0×10^7 PFU/mL	80	80	5.0×10^6 PFU/mL
5.0×10^6 PFU/mL	80	80	2.5×10^6 PFU/mL

Table 6. Sample preparation of SARS-CoV

Original concentration on the swab of 021401: 1.0×10^8 PFU/mL					
No.	**Conc. on the swab**	**Amount Added for each sample （μL）**	**Vol. of Extraction Sol. (μL)**	**Conc. Tested on Device**	**Swab Sample No.**
67	1.0×10^8PFU/mL	50	450	1.0×10^7PFU/mL (Dilution - 10×)	021401
68	2.0×10^7PFU/mL	50	450	2.0×10^6PFU/mL(Dilution - 50×)	021408
69	1.0×10^7PFU/mL	50	450	1.0×10^6 PFU/mL(Dilution - 100×)	021416
70	5.0×10^6PFU/mL	50	450	5.0×10^5 PFU/mL(Dilution - 200×)	021423
32	2.5×10^6PFU/mL	50	450	2.5×10^5 PFU/mL (Dilution - 400×)	021409

No.	**Swab Sample No.**	**Organism/virus**	**Conc.Tested on Device**	**Results**		
				Lot 1	Lot 2	Lot 3
67	021401	SARS-coronavirus	1.0×10^7PFU/mL (Dilution - 10×)	+	+	+
68	021408	SARS-coronavirus	2.0×10^6PFU/mL (Dilution - 50×)	+	+	+
69	021416	SARS-coronavirus	1.0×10^6 PFU/mL (Dilution - 100×)	+	+	+
70	021423	SARS-coronavirus	5.0×10^5 PFU/mL (Dilution - 200×)	+	+	+
32	021409	SARS-coronavirus	2.5×10^5 PFU/mL (Dilution - 400×)	-	-	-

In Silico Cross Reactivity (ANALYTICAL SPECIFICITY) Analysis

Due to lack of availability, wet testing for pneumocystis jirovecii, mycobacterium tuberculosis and human coronavirus HKU1 was not performed. To evaluate the degree of protein sequence homology,Basic Local Alignment Search Tool for in-silico analysis was used in this study.

Human coronavirus HKU1

Using the Reference Sequence (RefSeq) database built by the National Center for Biotechnology Information (NCBI), the nucleocapsid phosphoprotein amino acid sequence of SARS-CoV-2 isolate Wuhan-Hu-1 (RefSeq: YP_009724397.2) and human coronavirus HKU1 (RefSeq: YP_173242.1) were obtained. The homology between the query (i.e., SARS-CoV-2) and subject (i.e., coronavirus HKU1) sequences for the nucleocapsid phosphoprotein were assessed using Align Sequence Protein BLAST, a program managed by the NCBI that compares regions of local similarity between protein sequences and calculates the statistical significance of matches. The sequence similarity between human coronavirus HKU1 and SARS-CoV-2 virus nucleocapsid protein is 36.74%, homology is low,but the possibility of cross-reactivity cannot be ruled out.

Mycobacterium tuberculosis & Pneumocystis jirovecii

The homology between the nucleotide sequence of the SARS-CoV-2 isolate Wuhan-Hu-1 that codes for the nucleocapsid phosphoprotein (Locus: NC_045512; Location: 28,274 - 29,533) obtained from the NCBI was compared to the complete genomes of *M. tuberculosis* (Strain ATCC25618/H37Rv) and

P. jirovecii (strain RU7) using Translated BLAST. No significant sequence similarity to the SARS- CoV-2 virus nucleocapsid protein was found in pneumocystis jirovecii and mycobacterium tuberculosis, so there was no cross-reactivity.

Conclusion

There were no false negatives or false positives in the test results with Staphylococcus aureus、Streptococcus pyogenes, Measles Virus, Edmonston, Mumps virus, Mycoplasma pneumoniae, Human Metapneumovirus (hMPV), Human coronavirus OC43, Human coronavirus 229E, Influenza B (Victoria strain), Influenza B (Y strain), Influenza A (H1N1, 2009), Influenza A (H3N2), Epstein-Barr virus, Enterovirus 70, Human Rhinovirus B70, Respiratory syncytial virus A, Respiratory syncytial virus B, Streptococcus pneumoniae, Candida albicans, Chlamydia pneumoniae, Bordetella pertussis, Human coronavirus NL63, Legionella pneumophila, Haemophilus influenzae, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Staphylococcus epidermidis, Adenovirus Type 5, Adenovirus Type 3, Adenovirus Type 7, Human para-flu virus type-1, Human para-flu virus type-2, Human para-flu virus type-3, Human para-flu virus type-4, Paramyxovirus parotitis, Avian influenza virus (H7N9), Avian influenza virus (H5N1), Human Rhinovirus type 1, Human Rhinovirus type 14, Enterovirus CA16, Bordetella parapertussia and MERS-CoV at the concentration of *table 1.*， so the above

organisms or viruses tested by RapidFor SARS-CoV-2 Rapid Antigen Test Kit do not cross-react or interfere.

The cross-reactivity of SARS-CoV on the device was not an unexpected observation. An *in silico* analysis of the nucleocapsid phosphoprotein amino acid sequences of SARS-CoV (Reference Sequence, RefSeq: YP_009825061) and SARS-CoV-2 (RefSeq: YP_009724397) using Basic Local Alignment Search Tool (BLAST), a program managed by the National Center for Biotechnology Information (NCBI) that compares regions of local similarity between protein sequences and calculates the statistical significance of matches, demonstrates an estimated homology of 91% (382/422) across 94% (398/422) of the sequence. SARS-coronavirus occurs false positives result when the original concentration of the swab with SARS-coronavirus is above 2.5×10^5 PFU/mL. Considering the LoD of the test is 100 $TCID_{50}$/mL and $5.0x10^3$ cell copies/mL the estimated cross-reactivity with SARS is < 0.0275%.