COVID-19 Viral Antigen Rapid Test

Instructions For Use

REF DC0302

INTENDED USE

This product is a chromatographic immunoassay for the rapid and qualitative detection of SARS nucleocapsid antigens in nasal swabs from individuals who are suspected of COVID-19 within first 12 days of symptom onset.

Abnova's COVID-19 Viral Antigen Rapid Test does not differentiate SARS-CoV and SARS-CoV-2. Positive results indicate presence of viral antigens but clinical correlation is necessary. Positive results do not rule out bacterial or viral co-infection. Negative results should not be the sole basis of clinical management and should be confirmed with a molecular assay. Abnova's COVID-19 Viral Antigen Rapid Test is intended for use by trained personnel in clinical laboratories.

BACKGROUND

In 2019, a novel coronavirus was identified as the cause of an outbreak of severe respiratory disease in China. On February 11, 2020, the disease was officially named "Coronavirus Disease 2019" (COVID-19), also known as SARS-CoV-2.[1] The median incubation time is estimated to be 5 days with symptoms expected to be present within 12 days of infection.[2] The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, and shortness of breath.[3]

PRINCIPLE OF THE TEST

Abnova's COVID-19 Viral Antigen Rapid Test is a rapid 15 minutes chromatographic immunoassay for detection of SARS nucleocapsid antigens in the nasal swab specimens taken from patients suspected of COVID-19 within the first 12 days of symptom onset. The test detects but does not differentiate between the SARS-CoV and SARS-CoV-2 viruses. When the nasal swab specimens are processed by the extraction buffer and added to the Sample Zone, the SARS nucleocapsid antigens present in the specimens bind to the antibodies conjugated to the nanoparticles in the test strip. The antigen-conjugate complexes migrate across the test strip to the Result Zone and are capture by a line of antibodies bound on the membrane. The test is intended to be visually interpreted. A positive result is determined by a visible colored line at the Test "T" position and the Control "C" on the test strip. A negative result is determined by the absence of a visible colored line at the Test "T" position and the presence of a visible colored line at the Control "C" on the test strip. Control line must appear every time to ensure the quality of the sample processing. Abnova's COVID-19 Viral Antigen Rapid Test is validated for use for direct specimen testing without transport media.

MATERIALS AND SUPPLIES PROVIDED

Abnova COVID-19 Viral Antigen Rapid Test contains COVID-19 Antigen Testing Strips, Extraction Buffers, Droppers, Control Swabs and Instructions for Use.

25 Test Kit:

COVID-19 Antigen Testing Strips (25)

- Colloidal gold-labeled COVID-19 nucleocapsid murine monoclonal antibody
- COVID-19 nucleocapsid human monoclonal antibody
- Goat anti-murine polyclonal antibody

Extraction Buffers (25)

- Extraction reagent

Droppers (25)

- 100 µL Dropper for drawing sample mixture

Positive Control Swab (1)

- Non-infectious, recombinant viral nucleocapsid protein with less than 0.1% sodium azide

Negative Control Swab (1)

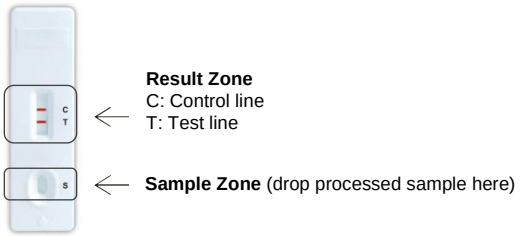
- Buffer with less than 0.1% sodium azide

Assay Documentation (1)

- Instructions for Use

COVID-19 Antigen Testing Strip	Extraction Buffer	Dropper	Positive Control Swab	Negative Control Swab
				

The Result Zone and Sample Zone of COVID-19 Antigen Testing Strip are shown below:



MATERIALS REQUIRED BUT NOT PROVIDED

- Nasal specimen sampling swabs
- Tube rack for specimens
- Timer or watch
- Personal protective equipments

EXPIRATION DATE

Date of manufacture, expiration date and lot number are indicated on the packaging. Expiration date is 6 months after the date of manufacture.

STORAGE ENVIRONMENT

- Store kit at room temperature 15°C - 30°C (59°F - 86°F) and avoid direct exposure to sunlight.
- Do not freeze or store the kit outside the temperature range described above.
- Do not open the kit until ready to use.
- Do not use the kit after the expiration date.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- This test has been authorized only for detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Each strip cassette, buffer vial, dropper, and control swab are for one-time use only. Dispose after use. DO NOT REUSE.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Test results are visually determined.
- Specimens must be collected and processed as indicated in the procedure section to avoid false test results.
- Positive and Negative Control Swabs are not be used for nasal specimen collection.
- Freshly collected specimen should be processed within 1 hour.
- This kit is NOT INTENDED for testing liquid sample such as wash or aspirate samples or swabs in transport media.
- Testing should be performed in an area with adequate ventilation.
- Sodium azide which is harmful if inhaled, swallowed, or exposed to skin. Wash with plenty of water if contact with the skin.
- Standard precautions and institutional guidelines should be followed in handling, storing, and disposing of all specimens and all blood and bodily fluids.
- Wear protective clothing, glove, and eye/face protection when handling the content of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, and handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at www.abnova.com.

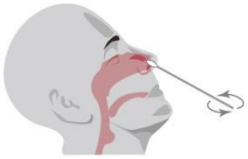
SPECIMEN COLLECTION

- Prior to collecting the nasal swab, the patient should be instructed to BLOW THEIR NOSE.
- Acceptable specimen for testing with this kit is FRESH nasal swab specimen collected from BOTH NASAL CAVITIES, and should be processed within 1 hour.
- Correct specimen collection and test procedure be diligently followed.

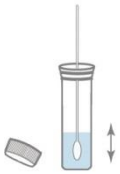
FRESH SPECIMEN SAMPLING PROCEDURE AND TEST

Nasal Swab Specimen Collection

1. Insert the swab tip up to 2.5 cm (1 inch) from edge of the nostril. Roll the swab along the mucosa inside the nostril 5 times for both nasal cavities

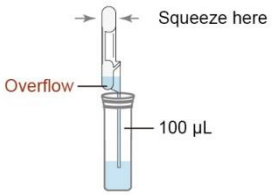


2. Insert the swab into the Extraction Buffer tube and plunge the swab up and down in the fluid for a minimum of 30 seconds, taking care not to splash contents out of the tube

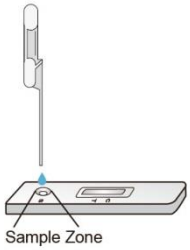


3. Remove the swab from the vial while rolling the swab head against the inside of the tube

4. Squeeze the top bulb of the dropper, place the dropper into the upper mixture, and release the bulb pressure to draw 100 uL mixed sample with a slight overflow to assure the desired volume.



5. Add the 100 uL mixed sample to the Sample Zone of the strip by squeezing the top bulb of the Dropper.



6. Read the test result at 15 minutes

DO NOT read after 20 minutes

POSITIVE AND NEGATIVE SWABS

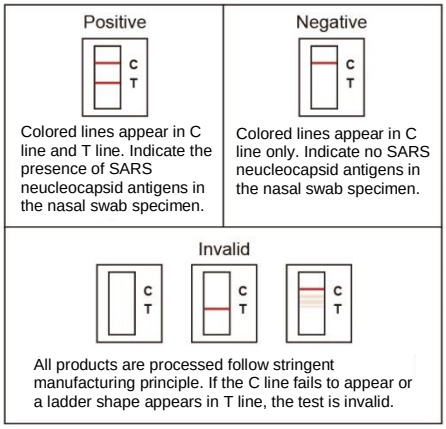
An external positive and negative control swabs are needed to ensure that test reagents are working and the test is correctly performed. A recombinant viral nucleocapsid protein is deposited on the positive control swab while the negative control swab is without protein. Abnova recommends that controls should be run once for each new kit lot, each new operator, and as required by internal quality control procedure and in accordance with local, state, and federal regulations or accreditation requirements.

TEST LIMITATIONS

- Freshly collected specimen should be processed and tested as soon as possible, and within one hour after specimen collection.
- Use of alternative swabs may result in false negative results.
- Positive test results do not rule-out co-infections with other pathogens.
- Negative test results do not eliminate possibility of SARS-CoV-2 infection and should be confirmed with an authorized molecular assay.
- Negative test results do not rule-in other non-SARS-CoV-2 viral or bacterial infection.
- Excess blood or mucous on the swab specimen may interfere with test performance and may yield a false positive result.
- False negative tests result may occur if the viral antigen is below the detection limit of the test or if sample was collected improperly.
- Specimens collected after day 12 of illness are more likely to be negative compared to a RT-PCR assay.
- Monoclonal antibodies may fail to detect or detect with less sensitivity SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated in asymptomatic individuals.

INTERPRETATION OF RESULTS

Result Zone of the COVID-19 Antigen Testing Strip indicates Test line (T line) Control line (C line). C line must appear to ensure the quality of sample processing. Please refer to the diagram below for interpretation:



Note: Report all positive results to the appropriate public health authorities. For invalid results, review the procedure and repeat the procedure with a new test. If the problem persists, discontinue using the test kit and contact local distributors and Abnova.

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

The performance of the Abnova COVID-19 Viral Antigen Rapid Test was established with 81 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients (within 12 days of onset) who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases. Nasal swabs were collected following the dual nares method and handled as described in FRESH SPECIMEN SAMPLING PROCEDURE AND TEST section. All specimens within a prespecified date range were selected and then sequentially tested in a blinded fashion. The performance of the Abnova COVID-19 Viral Antigen Rapid Test was compared to results of a nasopharyngeal swab tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of SARS-CoV-2.

Abnova COVID-19 Viral Antigen Rapid Test Results	Reference RT-PCR Results		
	POS	NEG	Total
POS	20	3	23
NEG	0	58	58
Total	20	61	81

PPA: 100% (C.I. 84%-100%)

NPA: 95% (C.I. 87%-98%)

OPA: 96% (C.I. 90%-99%)

EXPLANATION OF TERMS:

PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives

NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives

OPA: Overall Percent Agreement = True Positives + True Negatives / Total Samples

C.I.: Confidence Interval

LIMITED OF DETECTION (LOD)

The LOD for the Abnova's COVID-19 Viral Antigen Rapid Test was established using limiting dilutions of a viral sample inactivated by heat (ATCC heat-inactivated SARS-CoV-2 (VR-1986HK) lot # 7003767). The material was supplied at a concentration of 1.6 x 10^5 $TCID_{50}$/mL. In this study, designed to estimate the LOD of the assay when using a direct nasal swab specimen, the starting material was spiked into a volume of human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. An initial range finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested in the COVID-19 Viral Antigen Rapid Test using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™) Concentration	No. Positive/Total	% Positive
1.6 x 10^5 $TCID_{50}$/mL	3/3	100%
1.6 x 10^4 $TCID_{50}$/mL	3/3	100%
1.6 x 10^3 $TCID_{50}$/mL	0/3	0%
8 x 10^3 $TCID_{50}$/mL	3/3	100%
4 x 10^3 $TCID_{50}$/mL	0/3	0%
2 x 10^3 $TCID_{50}$/mL	0/3	0%
8 x 10^3 $TCID_{50}$/mL	20/20	100%

Starting Material Concentration Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
1.6 x 10^5 $TCID_{50}$/mL	8 x 10^3 $TCID_{50}$/mL	20/20	100%

Devices \ Virus titer /Results	Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™) Concentration	No. Positive/Total	% Positive
Abnova COVID-19 Viral Antigen Rapid Test	1.6 x 10^4 $TCID_{50}$/mL	3/3	100%
	8 x 10^3 $TCID_{50}$/mL	3/3	100%
BD Veritor System for Rapid Detection of SARS-CoV-2	1.6 x 10^4 $TCID_{50}$/mL	3/3	100%
	8 x 10^3 $TCID_{50}$/mL	0/3	0%

CROSS REACTIVITY

Cross reactivity of Abnova COVID-19 Viral Antigen Rapid Test was evaluated by testing various microorganisms (7), viruses (15), and negative nasal specimen matrix (1) with the Abnova COVID-19 Viral Antigen Rapid Test. Each organism and virus were tested in triplicate in the absence of heat-inactivated SARS-CoV-2. The final concentration of the organisms and viruses are in the Table below.

Cross Reactivity: COVID-19 Viral Antigen Rapid Test Wet testing		
Virus/Bacteria/Parasite*	Concentration	Cross-Reactive Results**
Adenovirus	1 x 10^5 $TCID_{50}$/mL	Negative
Enterovirus	1.1 x 10^5 pfu/mL	Negative
Human Coronavirus 229E	1 x 10^5 U/mL	Negative
Human Coronavirus NL63	5 x $10^{3.67}$ U/mL	Negative
Human Coronavirus OC43	1 x 10^5 $TCID_{50}$/mL	Negative
Human Metapneumovirus	1 x $10^{5.55}$ U/mL	Negative
Human Rhinovirus	1.1 x 10^5 pfu/mL	Negative
Influenza A H1N1	2.5 x 10^5 $TCID_{50}$/mL	Negative
Influenza A H3N2	2.5 x 10^5 $TCID_{50}$/mL	Negative
Influenza B	2.9 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza 1	1 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza 2	1 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza 3	5.2 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza 4b	1.6 x 10^4 $TCID_{50}$/mL	Negative
Respiratory Syncytial Virus	4 x 10^5 $TCID_{50}$/mL	Negative
Bordetella pertussis	6.37 x 10^6 cfu/mL	Negative
Candida albicans	3 x 10^6 cfu/mL	Negative
Haemophilus influenzae	7.87 x 10^6 cfu/mL	Negative
Legionella pneumophila	6.82 x 10^6 cfu/mL	Negative
Mycoplasma pneumoniae M129	3 x 10^6 CCU/mL	Negative
Streptococcus pneumoniae	2.26 x 10^6 cfu/mL	Negative
Streptococcus pyogenes	3.8 x 10^6 cfu/mL	Negative
Negative Nasal Matrix	N/A	Negative

*Coronavirus HKU1 was not tested in the cross-reactivity due to lack of availability. The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed that the only potential for homology is with the HKU1 nucleocapsid phosphoprotein. Homology is relatively low, at 36.7% across 82% of sequences, but cross reactivity cannot be ruled out.

**Testing was performed in triplicate. Based on the data generated by this study, the organism or viruses tested Abnova COVID-19 Viral Antigen Rapid Test do not cross-react.

HIGH DOSE HOOK EFFECT

As part of the LOD study the highest concentration of the heat-inactivated SAR-CoV-2 stock available (TCID50 of 1.6 x 10^5 per mL) was tested. There was no Hook effect detected.

ENDOGENOUS INTERFERENCE SUBSTANCES STUDIES

A study was performed for fourteen (14) potential substances found in the upper respiratory tract which do not cross-react or interfere with the detection of SARS-CoV-2 nasal swab specimen in Abnova's COVID-19 Viral Antigen Rapid Test. ATCC heat-inactivated SARS-CoV-2 (VR-1986HK) stock lot # 7003767 is used at 2xLOD for the interference study.

Substances	Concentration	Cross-Reactive Results	Interference Results
Oxymetazoline	5%	Negative	Positive
Blood	5%	Negative	Positive
Benzocaine	4 mg/mL	Negative	Positive
Fluticasone	5%	Negative	Positive
Menthol	5%	Negative	Positive
Triamcinolone	5%	Negative	Positive
Phenylephrine hydrochloride	5%	Negative	Positive
Oseltamivir	2.2 ug /mL	Negative	Positive
Mucin protein	2.5 mg /mL	Negative	Positive
Budesonide (Glucocorticoid)	5%	Negative	Positive
Saline	15%	Negative	Positive
Tobramycin	1.25 mg/mL	Negative	Positive
Zanamivir	225 ng /mL	Negative	Positive
Zicam Cold Remedy (Galphimia glauca, Luffa operculata, Sabadilla)	5%	Negative	Positive

PRECISION

Day 1								
Kit Lot	Operator	Sample	Sample Concentration	Result (C/T)		Expected Result (C/T)	Result Agreement	
				Viewer 1	Viewer 2		Viewer 1	Viewer 2
KA211	A	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2) Recombinant Protein diluted with Extraction Buffer	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)
			5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/Strong+	+/Strong+	+/Strong+	100% (3/3)	100% (3/3)
	B	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2) Recombinant Protein diluted with Extraction Buffer	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)
			5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/strong+	+/strong+	+/strong+	100% (3/3)	100% (3/3)

Day 2								
Kit Lot	Operator	Sample	Sample Concentration	Result (C/T)		Expected Result (C/T)	Result Agreement	
				Viewer 1	Viewer 2		Viewer 1	Viewer 2
KA212	A	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2) Recombinant Protein diluted with Extraction Buffer	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)
			5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/Strong+	+/Strong+	+/Strong+	100% (3/3)	100% (3/3)
	B	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2)	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)

		Recombinant Protein diluted with Extraction Buffer	5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/strong+	+/strong+	+/strong+	100% (3/3)	100% (3/3)

Day 3								
Kit Lot	Operator	Sample	Sample Concentration	Result (C/T)		Expected Result (C/T)	Result Agreement	
				Viewer 1	Viewer 2		Viewer 1	Viewer 2
KA213	A	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2) Recombinant Protein diluted with Extraction Buffer	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)
			5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/Strong+	+/Strong+	+/Strong+	100% (3/3)	100% (3/3)
	B	Extraction Buffer	0	+/-	+/-	+/-	100% (3/3)	100% (3/3)
		N (SARS-CoV-2) Recombinant Protein diluted with Extraction Buffer	3 ng/mL	+/low+	+/low+	+/low+	100% (3/3)	100% (3/3)
			5 ng/mL	+/moderate+	+/moderate+	+/moderate+	100% (3/3)	100% (3/3)
			10 ng/mL	+/strong+	+/strong+	+/strong+	100% (3/3)	100% (3/3)

QUALITY CONTROL

- The internal positive control line validates the immunological integrity of the testing strips, proper reagent function, and assures correct test procedure.
- The internal controls do not assess proper sample collection technique.

SYMBOLS

	Do not re-use		Do not use if package is damaged		Temperature limit: 15°C - 30°C
	Consult instruction for use		Manufacturer	REF	Catalog number
LOT	Lot number		Use by date		Date of manufacture
CE	CE Mark		25 tests	EC REP	Authorized Representative in the European Community
IVD	*In vitro* diagnostic medical device				

ADVERSE EVENTS

Reporting Adverse Events, including problems with test performance or results, to Abnova by submitting the online Adverse Events Form.

(http://www.abnova.com/support/AdverseEvents.asp)

REFERENCES

1. Centers for Disease Control and Prevention. About COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/cdcresponse/about-COVID-19.html
2. Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006.
3. Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application, Ann Intern Med. 2020

CE IVD

EC REP **mdi Europa GmbH**
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APPENDIX A: Sample Flex Study Design Details

1) Delay in Reading Time

Time after Sampling Loading \ Virus titer /Results	Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™) Concentration	No. Positive/Total	% Positive
3 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	1/5	20%
6 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%
9 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%
12 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%
15 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%
30 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%
45 min	0	0/5	0%
	2.4 x 10^4 $TCID_{50}$/mL	5/5	100%

2) Specimen Volume Variability

Volume of Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™) coating in swab	Result		Expected Result (C/T)	Result Agreement	
	Viewer 1	Viewer 2		Viewer 1	Viewer 2
25 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)
50 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)
100 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)

Titer of Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™): 2.4 x 10^4 $TCID_{50}$/mL (3X LOD)

3) Buffer Volume Variability

Volume of Extraction Buffer containing Heat-inactivated SARS-CoV-2 loading to Strip	Result		Expected Result (C/T)	Result Agreement	
	Viewer 1	Viewer 2		Viewer 1	Viewer 2
50 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)
100 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)
200 µL	+/+	+/+	+/+	100% (5/5)	100% (5/5)

Titer of Heat-inactivated SARS-CoV-2 (ATCC® VR-1986HK™): 2.4 x 10^4 $TCID_{50}$/mL (3X LOD)

4) Temperature and Humidity

Temperature and Humidity	Result		Expected Result (C/T)	Result Agreement	
	Viewer 1	Viewer 2		Viewer 1	Viewer 2
4°C and 80% RH	+/+ +/-	+/+ +/-	+/+	40% (2/5)	40% (2/5)
25°C and 50% RH	+/+	+/+	+/+	100% (5/5)	100% (5/5)
45°C and 30% RH	+/+ +/-	+/+ +/-	+/+	60% (3/5)	60% (3/5)

5) Disturbance During Analysis

Disturbance	Result		Expected Result (C/T)	Result Agreement	
	Viewer 1	Viewer 2		Viewer 1	Viewer 2
None	+/+	+/+	+/+	100% (5/5)	100% (5/5)
Dropping the device while the test is running	+/+	+/+	+/+	100% (5/5)	100% (5/5)