Product Registration File

Flowflex SARS-CoV-2 Antigen Rapid Test

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1 BACKGROUND

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

1.1 Test Principle

The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane strip based immunoassay for the detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 antibody conjugated with colored particles (SARS-CoV-2 Antibody conjugates), 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line are pre-coated with SARS-CoV-2 antibody, and the C line is pre-coated with a control line antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 antigens, if present in the specimen, will react with the SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

1.2 Intended Use

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

1.3 Storage

Store as packaged at room temperature or refrigerated (2-30 ℃). DO NOT FREEZE.

1.4 Stability

The SARS-CoV-2 Antigen Rapid Test is stable for 24 months from the date of production when stored properly in unopened pouch with desiccant.

1.5 Description of Test Methods

1.5.1 General Remarks

The Quality Control department performs testing according to written procedures.

1.5.2 Receiving Inspection and Control of Raw Materials

A sample batch of each raw material (chemicals, packaging and labeling) is inspected/tested (where applicable) for suitability and functionality. Primary packaging is inspected for correct dimensions, cleanliness and suitability. Only QC approved raw material is employed for production.

1.6 Composition of Product

The test cassette contains anti-SARS-CoV-2 antibodies. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

1.7 Manufacturing Procedure

A. Spray conjugate solution on the label pad.
B. Pre-coat anti-SARS-CoV-2 antibody and control antibody to the membrane attached on the backing card.
C. Treat the sample pad with sample pad solution.

D. Spray the conjugated anti-SARS-CoV-2 antibody on the label pad.

E. Laminate the label pad, absorbent pad, and sample pad on the backing card with membrane.

F. Cut the laminated card into strips and assemble the strip into the plastic housing.

G. Pack the test and desiccant into the pouch and seal.

H. Test the product according to the QC procedure and release the finished product.

There are no special manufacturing process considerations that affect safety and performance of the tests.

1.8 Quality Control

Run SARS-CoV-2 antigen positive control and negative control.

Sample	Test Result	C line
Positive control	Positive	C Line is visible within 120 seconds.
Negative nasal swab	Negative	
Positive Control Swab	Positive	
Negative Control Swab	Negative	
Extraction Buffer	Negative	

2 PERFORMANCE CHARACTERISTICS

2.1 IMPRECISION/REPRODUCIBILITY STUDY

Material：

SARS-CoV-2 Antigen Rapid Test:

Lot#1:COV0110005, Lot#2:COV0110006, Lot#3:COV0110007

SARS-CoV-2 Antigen Negative Sample (negative nasal matrix sample pool) Lot#: 20201104

SARS-CoV-2 Antigen Low Positive Sample (2×LoD) Lot#: COVAG200930L

SARS-CoV-2 Antigen Middle Positive Sample (6×LoD) Lot#: COVAG200930M

Method：

3 Lots of SARS-CoV-2 Antigen Rapid Test were tested according to the package insert by 3 operators. Each operator performed 2 tests on each control for 5 days in 2 sites in China. Total 180 tests were performed per each control: 2 replicates X 5 days X 3 lots X 3 operators X 2 sites=180 tests.

Acceptance Criteria：

Negative samples will generate negative results.

Positive samples will generate positive results.

C line is visible within 120 seconds.

Test Results：

Sample	Site	Operator	Lot 1									
			Day1		Day2		Day3		Day4		Day5	
Middle Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Low Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Negative Sample	a	A	-	-	-	-	-	-	-	-	-	-
		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-
	b	A	-	-	-	-	-	-	-	-	-	-
		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-

Note: C line is visible within 120 seconds.

Sample	Site	Operator	Lot 2									
			Day1		Day2		Day3		Day4		Day5	
Middle Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Low Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Negative	a	A	-	-	-	-	-	-	-	-	-	-

Sample		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-
	b	A	-	-	-	-	-	-	-	-	-	-
		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-

Note: C line is visible within 120 seconds.

Sample	**Site**	**Operator**	**Lot 3**									
			Day1		**Day2**		**Day3**		**Day4**		**Day5**	
Middle Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Low Positive Sample	a	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
	b	A	+	+	+	+	+	+	+	+	+	+
		B	+	+	+	+	+	+	+	+	+	+
		C	+	+	+	+	+	+	+	+	+	+
Negative Sample	a	A	-	-	-	-	-	-	-	-	-	-
		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-
	b	A	-	-	-	-	-	-	-	-	-	-
		B	-	-	-	-	-	-	-	-	-	-
		C	-	-	-	-	-	-	-	-	-	-

Note: C line is visible within 120 seconds.

Summary of results tested intro lot, between lots, between-days, between-sites and between-operators:

Samples	**Lot 1**	**Lot 2**	**Lot 3**
Middle Positive Sample	60/60 positive	60/60 positive	60/60 positive
Low Positive Sample	60/60 positive	60/60 positive	60/60 positive
Negative Sample	60/60 negative	60/60 negative	60/60 negative

Conclusion：

All three lots tested between-days, between-sites and between-operators identified the samples 100% correctly as negative or positive.

2.2 CLINICAL STUDY

2.1 Nasal swab samples clinical study

Material：

SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

Comparison method:

TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.

CDC 2019-nCoV RT-PCR, ABI 7500DX, FDA authorized RT-PCR test for emergency use

Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.

Nasal swab samples from infected patients and non-infected patients

Method：

The clinical performance of the SARS-CoV-2 Antigen Rapid Test was evaluated at four (4) investigational sites in U.S and two (2) investigational sites in China using a total of 605 nasal swab specimens collected from the patients at multiple sites in U.S and China. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled. The nasal swabs were randomized and blinded tested by operators following product package insert. A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

Acceptance Criteria：

Total Sensitivity: ≥85%

Total Specificity: ≥98%

Test Results:

Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
SARS-CoV-2 Antigen Rapid Test Test Results	Negative	433	5	438
	Positive	2	165	167
	Total	435	170	605

Relative Sensitivity: 97.1% (95% CI: 93.1%-98.9%)

Relative Specificity: 99.5% (95% CI: 98.2%-99.9%)

Accuracy: 98.8% (95% CI: 97.6%-99.5%)

Positive results to be reported by different Ct value range

Ct value	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
≤27	86	50.6%	86	100%
27-30	38	22.4%	38	100%
>30-33	29	17.1%	27	93.1%
>33	9	5.3%	6	66.7%

Note: There are eight samples only have the PCR result of positive and no Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 93.1% for samples with Ct value from >30 to 33. For samples with Ct value >33, the PPA is 66.7%.

Summary, positive samples with Ct value ⩽33 has a higher positive percent agreement (PPA) of 98.7% (n=153).

Positive results to be reported by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
0-3	81	46.3%	80	98.8%
4-7	62	37.0%	60	96.8%
>7	19	11.7%	17	89.5%

Note: There are four patients is asymptomatic individuals. And there are four patients lack “Days Since Symptom Onset” information.

Conclusions:

Using a total of 605 specimens tested at multiple sites in U.S and China, the SARS-CoV-2 Antigen Rapid Test has sensitivity of 97.1%, specificity of 99.5%, and accuracy of 98.8% when comparing with FDA EUA RT-PCR.

2.2 Nasopharyngeal swab samples clinical study

Material：

SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

Comparison method:

Hologic Panther SARS-CoV-2 (T000896), FDA authorized RT-PCR test for emergency use.

Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.

Nasopharyngeal swab samples from infected patients and non-infected patients

Method:

The clinical performance of the SARS-CoV-2 Antigen Rapid Test was evaluated at one (1) investigational sites in U.S and two (2) investigational sites in China using a total of 299 nasopharyngeal swab specimens collected from the patients at multiple sites in U.S and China. The nasopharyngeal swabs were randomized and blinded tested with SARS-CoV-2 Antigen Rapid Test by operators following product package insert. And all the specimens were also confirmed with an EUA RT- PCR as a comparator method.

The performance of the SARS-CoV-2 Antigen Rapid Test as compared to the RT-PCR comparator method are presented in the table below:

Acceptance Criteria:

Total Sensitivity: ≥85%

Total Specificity: ≥98%

Test Results:

Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
SARS-CoV-2 Antigen Rapid Test Test Results	Negative	175	3	178
	Positive	1	120	121
	Total	176	123	299

Relative Sensitivity: 97.6% (95% CI: 92.8% to 99.5%)

Relative Specificity: 99.4% (95% CI: 96.5% to 99.9%)

Accuracy: 98.7% (95% CI: 96.5% to 99.6%)

Conclusions:

Using a total of 299 specimens tested at multiple sites in U.S and China, the SARS-CoV-2 Antigen Rapid Test has sensitivity of 97.6%, specificity of 99.4%, and accuracy of 98.7% when comparing with FDA EUA RT-PCR.

2.3 MATRIX EQUIVALENCE STUDY

Materials：

SARS-CoV-2 Antigen Rapid Test, Lot#3:202009201

SARS-CoV-2 viral culture: Lot#324443, Titer 3.80×10^6 $TCID_{50}$/mL

Negative nasal matrix sample pool

Negative nasopharyngeal matrix sample pool

Method：

Diluted the high concentration SARS-CoV-2 virus culture with the negative nasal matrix sample pool and negative nasopharyngeal matrix sample pool respectively to $2.56*10^3$ $TCID_{50}$/mL. And then diluted the $2.56*10^3$ $TCID_{50}$/mL sample with corresponding matrix sample pool to one low positive (3 x LOD) and three moderately positive (5 x LOD, 6 x LOD and 7 x LOD). Blinding and randomization of the four positive nasal specimens, four positive nasopharyngeal specimens, one negative nasal specimen and one negative nasopharyngeal specimen were tested in duplicate, and compare the results between the matrices.

Acceptance Criteria:

There is no difference between nasal and nasopharyngeal swab specimens.

Test Results：

Sample	**Nasal Specimen**		**Nasopharyngeal Specimen**	
Negative	-	-	-	-
Low positive (3 x LOD)	+	+	+	+
Moderately positive (5 x LOD)	+	+	+	+
Moderately positive (6 x LOD)	+	+	+	+
Moderately positive (7 x LOD)	+	+	+	+

Conclusion:

According to the test result above, there is no difference between nasal and nasopharyngeal swab specimens for SARS-CoV-2 Antigen Rapid Test.

2.4 LOD STUDY

Material:

SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201

SARS-CoV-2 viral culture:

Lot#	Titer	PCR value after diluted to $1.6*10^2$ $TCID_{50}$/mL	PCR Test Result after diluted to $1.6*10^2$ $TCID_{50}$/mL
Lot#324443	3.80×10^6 $TCID_{50}$/mL	$2.56*10^4$copies/mL	Positive

Note：Titer was determined by $TCID_{50}$ Assay.

Method：

The LOD study for nasal and nasopharyngeal swab specimen were evaluated using products from three different lots respectively. Six different diluted concentration (8*10, $1.6*10^2$, $3.2*10^2$, $6.4*10^2$, $1.28*10^3$, $2.56*10^3$ $TCID_{50}$/mL) of SARS-CoV-2 virus culture samples were assayed in 10 replicates with every lot of product respectively. Total 30 tests were performed for each sample. Define the minimum concentration with⩾ 95% detectable rate as the minimum detectability (LoD).

Acceptance Criteria：

The LoD of SARS-CoV-2 Antigen Rapid Test should be ⩽ $7.5*10^2$ $TCID_{50}$/mL.

Test Result：

For nasal swab specimens:

Concentration	**Lot**	**Test Result**										**Detectable rate**
$2.56*10^3$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$1.28*10^3$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$6.4*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$3.2*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$1.6*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	96.7% (29/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	-	+	+	+	+	+	+	+	
8*10 $TCID_{50}$/mL	**Lot 1**	-	-	-	-	-	-	-	-	-	-	0% (0/30)
	Lot 2	-	-	-	-	-	-	-	-	-	-	

	Lot 3	-	-	-	-	-	-	-	-	-	-	

For nasopharyngeal swab specimens:

Concentration	**Lot**	**Test Result**										**Detectable rate**
$2.56*10^3$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$1.28*10^3$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$6.4*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$3.2*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
$1.6*10^2$ $TCID_{50}$/mL	**Lot 1**	+	+	+	+	+	+	+	+	+	+	100% (30/30)
	Lot 2	+	+	+	+	+	+	+	+	+	+	
	Lot 3	+	+	+	+	+	+	+	+	+	+	
8*10 $TCID_{50}$/mL	**Lot 1**	-	-	-	-	-	-	-	-	-	-	0% (0/30)
	Lot 2	-	-	-	-	-	-	-	-	-	-	
	Lot 3	-	-	-	-	-	-	-	-	-	-	

Conclusion：

According to the test result above, the LoD value of SARS-CoV-2 Antigen Rapid Test is confirmed as $1.6*10^2$ $TCID_{50}$/mL for nasal and nasopharyngeal swab specimens.

2.5 INTERFERENCE

Material：

SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

Heat inactivated SARS-CoV-2 virus: 1.51×10^6 $TCID_{50}$/mL, Isolate USA-WA1/2020, Lot#324615

Negative nasal matrix sample pool

Method：

Test the interference substances in the absence and presence of heat inactivated SARS-CoV-2 virus. These substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx.

The negative samples were prepared by spiking each substance into the negative nasal matrix sample pool to the test concentration listed in the table below. The low positive samples were prepared by spiking each substance and heat inactivated SARS-CoV-2 virus into the negative nasal matrix sample pool to the test concentration in the presence of low positive (3x LoD) of heat inactivated SARS-CoV-2 virus. Each sample was tested according to the package insert in triplicate with SARS-CoV-2 Antigen Rapid Test.

Acceptance Criteria：

No interference with the substances that naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity.

Test Results：

Interfering Substance	**Active Ingredient**	**Concentration**	**Test Results** (in the absence of SARS-CoV-2 virus)	**Test Results** (in the presence of SARS-CoV-2 virus)
Endogenous	Biotin	2.4 mg/mL	3/3 negative	3/3 positive
	Mucin	0.5% w/v	3/3 negative	3/3 positive
	Whole Blood	4% v/v	3/3 negative	3/3 positive
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	3/3 negative	3/3 positive
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	3/3 negative	3/3 positive
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	3/3 negative	3/3 positive
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	3/3 negative	3/3 positive
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	3/3 negative	3/3 positive
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	3/3 negative	3/3 positive
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	3/3 negative	3/3 positive
NasalCrom Nasal Spray	Cromolyn	15% v/v	3/3 negative	3/3 positive
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	3/3 negative	3/3 positive
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	3/3 negative	3/3 positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negative	3/3 positive

Antibiotic	Mupirocin	10 mg/mL	3/3 negative	3/3 positive
Tamiflu	Oseltamivir Phosphate	5 mg/mL	3/3 negative	3/3 positive
Antibiotic	Tobramycin	4 μg/mL	3/3 negative	3/3 positive
Mometasone Furoate Nasal Spray	Mometasone Furoate	5%v/v	3/3 negative	3/3 positive
Physiological Seawater Nasal Cleaner	NaCl	15%v/v	3/3 negative	3/3 positive

Conclusion：

The results show that the interfering substances tested do not cross-react and interfere to SARS-CoV-2 Antigen Rapid Test.

2.6 HOOK EFFECT

Materials:

SARS-CoV-2 Antigen Rapid Test, Lot# 202009001

Heat inactivated SARS-CoV-2 virus: 1.51×10^6 $TCID_{50}$/mL, Isolate USA-WA1/2020, Lot#324615

Negative nasal matrix sample pool

Negative nasopharyngeal matrix sample pool

Method：

The heat-inactivated SARS-CoV-2 virus was diluted in the nasal matrix sample pool and nasopharyngeal matrix sample pool respectively to generate a corresponding high positive sample with 1.43×10^5 $TCID_{50}$/mL. Then dilute these high positive samples with corresponding negative matrix sample pool with serial dilutions. Test each sample according to the package insert in 3 replicates with the SARS CoV-2 Antigen Rapid Test.

Acceptance Criteria：

Sample with very high levels of SARS-CoV-2 virus culture will not generate negative result.

Test Results：

For Nasal Swab Specimens:

Dilution Rate	Test result		
1.43×10^5 $TCID_{50}$/mL	+	+	+
2.86×10^4 $TCID_{50}$/mL	+	+	+
5.72×10^3 $TCID_{50}$/mL	+	+	+
2.86×10^3 $TCID_{50}$/mL	+	+	+
1.43×10^3 $TCID_{50}$/mL	+	+	+
7.15×10^2 $TCID_{50}$/mL	+	+	+
3.58×10^2 $TCID_{50}$/mL	+	+	+

For Nasopharyngeal Swab Specimens:

Dilution Rate	Test result		
1.43 x 10^5 $TCID_{50}$/mL	+	+	+
2.86 x 10^4 $TCID_{50}$/mL	+	+	+
5.72 x 10^3 $TCID_{50}$/mL	+	+	+
2.86 x 10^3 $TCID_{50}$/mL	+	+	+
1.43 x 10^3 $TCID_{50}$/mL	+	+	+
7.15 x 10^2 $TCID_{50}$/mL	+	+	+
3.58x 10^2 $TCID_{50}$/mL	+	+	+

Conclusion：

No high dose hook effect was observed when tested with up to a concentration of 1.43 x 10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with SARS-CoV-2 Antigen Rapid Test.

2.7 CROSS REACTIVITY STUDY AND MICROBIAL INTERFERENCE

Material：

SARS-CoV-2 Antigen Rapid Test, Lot#202009001

Negative nasal matrix sample pool

Method：

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat inactivated SARS-CoV-2 virus at low positive level. Each sample was tested according to packing insert in triplicate with SARS-CoV-2 Antigen Rapid Test.

Test Results：

Potential Cross -Reactant		**Test Concentration**	**Cross-Reactivity** (in the absence of SARS-CoV-2 virus)	**Interference** (in the presence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14 x 10^6 TCID50/mL	No 3/3 negative	No 3/3 positive
	Enterovirus	9.50 x 10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus 229E	1.04 x 10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus OC43	2.63 x 105 TCID50/mL	No 3/3 negative	No 3/3 positive

	Human coronavirus NL63	1.0×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Human Metapneumovirus	1.25×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	MERS-coronavirus	7.90×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Influenza A	1.04×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Influenza B	1.04×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 1	1.25×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 2	3.78×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 3	1.0×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 4	2.88×10^6 TCID50/mL	No 3/3 negative	No 3/3 positive
	Respiratory syncytial virus	3.15×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	Rhinovirus	3.15×10^5 TCID50/mL	No 3/3 negative	No 3/3 positive
	SARS-coronavirus	1×10^5 copies/mL	Yes 3/3 positive	No 3/3 positive
	Human coronavirus- HKU1	1×10^5 copies/mL	No 3/3 negative	No 3/3 positive
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia trachomatis	3.13×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Haemophilus influenzae	1.36×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Legionella pneumophila	4.08×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus aureus	1.38×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	No	No

			3/3 negative	3/3 positive
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No 3/3 negative	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Pseudomonas aeruginosa	1.87 x 10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia pneumoniae	1 ×10^6 IFU/ml	No 3/3 negative	No 3/3 positive
Yeast	Candida albicans	1.57 x 10^8 CFU/mL	No 3/3 negative	No 3/3 positive
Pooled human nasal wash			No 3/3 negative	No 3/3 positive

Conclusion：

No cross-reactivity or interference was observed with the above microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

2.8 READ TIME FLEX

Material：

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005

SARS-CoV-2 Antigen Negative Sample Lot#: 20201104

SARS-CoV-2 Antigen Low Positive Sample Lot#: COVAG200930L

SARS-CoV-2 Antigen Middle Positive Sample Lot#: COVAG200930M

Method：

SARS-CoV-2 Antigen negative, middle and low positive sample were tested with SARS-CoV-2 Antigen Rapid Test according to package insert. Each test was performed in triplicate. The test results were recorded at 5, 10, 15, 20, 30 and 40 minutes.

Acceptance Criteria：

Negative sample generates negative result

Positive sample generates positive result

C line is visible within 120 seconds

Test Results：

Sample	5min			10min			15min		
Negative	-	-	-	-	-	-	-	-	-
Low Positive	-	-	-	+	+	+	+	+	+
Middle Positive	+	+	+	+	+	+	+	+	+
N/A	C line is visual within 120 seconds								
Sample	20min			30min			40min		
Negative	-	-	-	-	-	-	-	-	-
Low Positive	+	+	+	+	+	+	+	+	+
Middle Positive	+	+	+	+	+	+	+	+	+
N/A	C line is visual within 120 seconds								

Conclusion:

The results are stability between 10~40mins, the suggested reading time is 15~30 mins.

2.9 SAMPLE VOLUME FLEX STUDY

Material：

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005

SARS-CoV-2 Antigen Negative Sample Lot#: 20201104

SARS-CoV-2 Antigen Low Positive Sample Lot#: COVAG200930L

SARS-CoV-2 Antigen Middle Positive Sample Lot#: COVAG200930M

Method：

SARS-CoV-2 Antigen negative, middle and low positive sample were tested with SARS-CoV-2 Antigen Rapid Tested in the following method: different volume of sample (2 drops, 3 drops, 4 drops, 5 drops and 6 drops) was added into specimen well respectively. Each test was performed according to package insert in 3 replicates. Observed if C line is visible within 120 seconds.

Acceptance Criteria：

Negative sample generates negative result
Positive sample generates positive result
C line is visible within 120 seconds

Test Results：

Sample Volume		**Negative**	**Middle**	**Low**
2 drops	Tline	Invalid Result	Invalid Result	Invalid Result
	Cline	C line is not visual within 120 seconds		

3 drops	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
4 drops	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
5 drops	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
6 drops	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								

Conclusion:

The results show that the sample <3 drops is insufficient and sample volume of 3 - 6 drops have no difference. So, the suggested sample volume is 4 drops.

2.10 TEMPERATURE FLEX STUDY

Materials:

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005

SARS-CoV-2 Antigen Negative Sample Lot#: 20201104

SARS-CoV-2 Antigen Low Positive Sample Lot#: COVAG200930L

SARS-CoV-2 Antigen Middle Positive Sample Lot#: COVAG200930M

Methods:

Keep the SARS-CoV-2 Antigen Rapid Test cassette, extraction buffer and samples at the following different conditions: 2~8℃, 15℃, 20℃, 30℃, 35℃ for 1 hour. Then test the SARS-CoV-2 Antigen Rapid Test with each sample at each condition according to package insert in triplicate. Observed if C line is visible within 120 seconds.

Acceptance Criteria：

Negative sample generates negative result
Positive sample generates positive result
C line is visible within 120 seconds.

Test Results：

Temperature	Item	Negative			Low Positive			Middle Positive		
2~8℃	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
15℃	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								

20℃	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
30℃	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								
35℃	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visual within 120 seconds								

Conclusion：

The results show that there is no difference when test at temperature from 2~8℃ to 35℃. SARS-CoV-2 Antigen Rapid Test can be tested in the temperature range of 15~30℃.

2.11 OPEN POUCH STABILITY STUDY

Materials:

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005

SARS-CoV-2 Antigen Negative Sample Lot#: 20201104

SARS-CoV-2 Antigen Low Positive Sample Lot#: COVAG200930L

SARS-CoV-2 Antigen Middle Positive Sample Lot#: COVAG200930M

Methods:

Unpackaged SARS-CoV-2 Antigen Rapid Test cassettes were stored in constant temperature humidity oven and the condition shown as below:

1) Temperature 15±3℃ and humidity 10%±3%;

2) Temperature 15±3℃ and humidity 80%±3%;

3) Temperature 30±3℃ and humidity 10%±3%;

4) Temperature 30±3℃ and humidity 80%±3%;

Then run the test at each condition at different time points separately: 0min, 15mins, 30mins, 45mins, 60mins and 75mins.

Each sample was tested according to package insert in triplicate at each time point.

Acceptance Criteria：

C line is visible within 120 seconds

Negative sample generates negative result

Positive sample generates positive result

Test Results：

Exposure 0 minute (Control Condition):

Exposure Condition	Item	Negative	Low Positive	Middle Positive

Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Exposure for 15 minutes:

Exposure Condition	Item	Negative			Low Positive			Middle Positive		
Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Exposure for 30 minutes:

Exposure Condition	Item	Negative			Low Positive			Middle Positive		
Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Exposure for 45 minutes:

Exposure Condition	Item	Negative			Low Positive			Middle Positive		
Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Exposure for 60 minutes:

Exposure Condition	Item	Negative			Low Positive			Middle Positive		
Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Exposure for 75 minutes:

Exposure Condition	Item	Negative			Low Positive			Middle Positive		
Temperature 13.5℃, humidity 12%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 13.4℃, humidity 81%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								
Temperature 31.5℃, humidity 11%	Tline	-	-	-	+	+	+	+	+	+
	Cline									
Temperature 30.4℃, humidity 80%	Tline	-	-	-	+	+	+	+	+	+
	Cline	C line is visible within 120 seconds								

Conclusion:

According to the results above, there is no difference observed when perform the test at different temperature from 15-30℃ and humidity from 10%-80% condition. SARS-CoV-2 Antigen Rapid Test cassette can be tested within 1 hour after the pouch have been opened. .

2.12 OPEN POUCH STABILITY STUDY (FOR CONTROL SWAB)

Materials:

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005

Positive control swab, lot# COV0110005

Negative control swab, lot# COV0110005

Extraction Buffer, Lot#:COV0110005

Methods:

Unpackaged negative and positive control swabs were stored in constant temperature humidity oven and the condition shown as below:

1) Temperature 15±3℃ and humidity 10%±3%;

2) Temperature 15±3℃ and humidity 80%±3%;

3) Temperature 30±3℃ and humidity 10%±3%;

4) Temperature 30±3℃ and humidity 80%±3%;

Then run the test at each condition at different time points separately: 0min, 15mins, 30mins, 45mins, 60mins and 75mins.

Each control swab was tested according to package insert in triplicate at each time point.

Acceptance Criteria：

Negative control swab generates negative result
Positive control swab generates positive result

Test Results：

Exposure 0 minute (Control Condition):

Exposure Condition	Negative Control Swab			Positive Control Swab		
Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Exposure for 15 minutes:

Exposure Condition	Negative Control Swab			Positive Control Swab		
Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Exposure for 30 minutes:

Exposure Condition	Negative Control Swab			Positive Control Swab		
Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Exposure for 45 minutes:

Exposure Condition	Negative Control Swab	Positive Control Swab

Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Exposure for 60 minutes:

Exposure Condition	Negative Control Swab			Positive Control Swab		
Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Exposure for 75 minutes:

Exposure Condition	Negative Control Swab			Positive Control Swab		
Temperature 13.6℃, humidity 12.5%	-	-	-	+	+	+
Temperature 14.2℃, humidity 82.2%	-	-	-	+	+	+
Temperature 30.2℃, humidity 12.4%%	-	-	-	+	+	+
Temperature 30.5℃, humidity 81.1%%	-	-	-	+	+	+

Conclusion:

According to the results above, there is no difference observed when perform the test at different temperature from 15-30℃ and humidity from 10%-80% condition. The control swabs can be tested within 1 hour after the pouch have been opened. .

2.13 STABILITY STUDY

Materials：

SARS-CoV-2 Antigen Rapid Test,

Lot#1: 202009101, Lot#2: 202009001, Lot#3: 202009201

SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N

SARS-CoV-2 Antigen Low Positive Sample Lot#: COVAG200904P3

SARS-CoV-2 Antigen Middle Positive Sample Lot#: COVAG200904P2

Method：

Accelerated stability study of the SARS-CoV-2 Antigen Rapid Test including test cassettes, extraction buffer tube and control swabs was evaluated together using products from three lots. These products were placed in an incubator with the temperature calibrated at 55℃. A series of stability tests were performed at 1st-5th week at

55℃. Products were assayed using different levels of positive and negative samples. Testing at each specific time interval in triplicate for each specimen according to the package insert.

Real time stability of the SARS-CoV-2 Antigen Rapid Test including test cassettes, extraction buffer tube and control swabs was evaluated using products from three different lots. These products were stored at 2-8℃ and 30 ±3℃. A series of stability tests are being performed at 0, 3, 6, 9, 12, 15, 18, 21, 24, and 27 months. Tests are assayed using different levels of positive and negative standards. Testing at each specific time interval in triplicate for each specimen.

Acceptance Criteria:

Negative sample will be rated as negative.

Negative control swab will be rated as negative.

Any positive sample will be rated as positive.

Positive control swab will be rated as positive.

C line is visible within 2 minutes.

Test Results：

Accelerate stability study:

Sample	0 day								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	7 days								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+

Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	14 days								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	21 days								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	28 days								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	35 days								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+

Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Real time stability study:

Sample	0 day								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Negative specimens	0 day								
	Lot 1			Lot 2			Lot 3		
Negative specimens from volunteer-1	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-2	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-3	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-4	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-5	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-6	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-7	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-8	-	-	-	-	-	-	-	-	-
Negative specimens from volunteer-9	-	-	-	-	-	-	-	-	-
Negative specimens	-	-	-	-	-	-	-	-	-

from volunteer-10									

Note: C lines are all visible within 2 minutes

Sample	3 months (2~8℃)								
	Lot1			Lot2			Lot3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	3 months (30℃)								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	6 months (2~8℃)								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+
Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Sample	6 months (30℃)								
	Lot 1			Lot 2			Lot 3		
Middle Positive Sample	+	+	+	+	+	+	+	+	+

Low Positive Sample	+	+	+	+	+	+	+	+	+
Negative Sample	-	-	-	-	-	-	-	-	-
Positive Control Swab	+	+	+	+	+	+	+	+	+
Negative Control Swab	-	-	-	-	-	-	-	-	-

Note: C lines are all visible within 2 minutes

Conclusion:

The results show that SARS-CoV-2 Antigen Rapid Test, including test cassette, extraction buffer tubes and control swabs are stable at 55℃ for 35 days, so the shelf life of SARS-CoV-2 Antigen Rapid Test can be estimated at least 24 months.

And the real time stability is still in progress and scheduled to be finished at December, 2022.