Flowflex™ SARS-CoV-2 Antigen Rapid Test

Evaluation Report

November 2020

Flow*flex* SARS-CoV-2 Antigen Rapid Test Evaluation Report

The Flow*flex* SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal 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 Flow*flex* 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 more than seven days post symptom onset 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 Flow*flex* SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

1. **Purpose:** To evaluate the performance of the Flow*flex* SARS-CoV-2 Antigen Rapid Test

2. **Material:**

Materials	Lot		
SARS-CoV-2 Antigen Rapid Test	202009101	202009001	202009201
Extraction Buffer	202008001	202008002	202008003

3. **Study procedure and results**

3.1 Imprecision/reproducibility Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1

Procedure:

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.

Test results:

SARS-CoV-2 Samples	Lot 1	Lot 2	Lot 3
High Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Mid Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Low Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Neg	- / 60 replicates	- / 60 replicates	- / 60 replicates

Conclusions:

All three lots identified the samples 100% correctly as negative or positive.

3.2 Limit of Detection (LOD)

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 viral culture

Procedure:

1. Sample Application Method: Apply 4~5 drops (approximately 100~125 ul) of sample to the sample well on the test cassette, then start the timer, read the result at 15-20 minutes.
2. Dilute the high concentration SARS-CoV-2 viral culture with the Extraction Buffer.
3. Use 3 lots of SARS-CoV-2 antigen rapid test to test the samples, and every sample is tested in 10 replicates. Calculate the detectable rate for each sample.
4. The minimum concentration with ≥95% detectable rate is defined as the minimum detectability (LOD).

Test results:

Culture sample:

Concentration	Lot	Test Result	Detectable rate
2.56×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.28×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	

6.4 x 10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
3.2 x 10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.6 x 10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	96.7% (29/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ 9 replicates / - 1 replicate	
8 x 10 $TCID_{50}$/mL	**Lot 1**	- / 10 replicates	0% (0/30)
	Lot 2	- / 10 replicates	
	Lot 3	- / 10 replicates	

Conclusion:

According to the test result, the LOD is 1.6 x 10^2 TCID50/mL

3.3 **Clinical study – nasal swabs**

A multi-site clinical study was conducted to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test, and the results are shown below.

Site 1 Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method: RT-PCR, Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), manufactured by Sansure BioTech Inc.
- Extraction Buffer, Lot1#:202008001
- Nasal swab samples from infected patients and non-infected patients

Site 1 Procedure:

1. Study was conducted in Hangzhou, China
    - 304 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All the samples were confirmed with RT-PCR.
    - 34 positive clinical nasal swabs collected from patients. 29 samples with Ct counts <33, 5 samples with Ct counts ≥33.

2. Following product package insert, performed the test and read the result at 15-20 minutes.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive*	Total
Flow*flex* Test Results	Negative	269	1	270
	Positive	1	33	34
	Total	270	34	304

Site 2 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.
- Nasal swab samples from infected patients and non-infected patients

Site 2 Procedure:

1. Study is being conducted in multiple U.S. sites in California and Florida, and it is ongoing. So far, 125 clinical nasal swabs were collected from patients who were suspected of COVID-19 (within 7 days of onset). All the samples were confirmed with RT-PCR method.
2. Following product package insert, performed the test and read the result at 15-20 minutes.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	32	3*	35
	Positive	1	89	90
	Total	33	92	125

***3 samples with PCR CT value 33.97 – 33.99**

Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	301	4	305
	Positive	2	122	124
	Total	303	126	429

Conclusions:

The sensitivity, specificity, and accuracy are meeting MHRA acceptable requirement, which has sensitivity greater than 80% and specificity greater than 95%.

	Performance	95% CI
Sensitivity	96.8% (122/126)	92.1%-99.1%
Specificity	99.3% (301/303)	97.6%-99.9%
Accuracy	98.6% (423/429)	97.0% -99.5%

3.4 Endogenous Interfering Substances

To determine if the substances that naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity interfere with Flow*flex* SARS-CoV-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot# 102820
- Pooled human negative clinical matrix

Procedure 1: Test the endogenous substances in the absence of heat inactivated SARS-Cov-2 virus.

The samples were prepared by spiking each substance into the human negative clinical matrix to the target concentration listed in the table below. Each sample was tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test according to the package insert.

Test Results:

No cross-reactivity was observed with the endogenous interfering substances when tested at the concentration presented in the table below.

Procedure 2: Test the endogenous substances in the presence of heat inactivated SARS-CoV-2 virus.

The samples were prepared by spiking each substance and heat inactivated SARS-Cov-2 virus into the human negative clinical matrix to the target concentration in the presence of heat inactivated SARS-CoV-2 virus at 9.71 x 10^2 TCID50/mL. Each sample was tested in triplicate according to the package insert.

Test Results:

No interference was observed.

Endogenous Interference Substances Study Results

Interfering Substances	Active Ingredient	Concentration	Cross-Reactive Results			Interference Results		
Endogenous	Mucin	0.5% w/v	-	-	-	+	+	+
	Whole Blood	4% v/v	-	-	-	+	+	+
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	-	-	-	+	+	+
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	-	-	-	+	+	+
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	-	-	-	+	+	+
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	-	-	-	+	+	+
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	-	-	-	+	+	+
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	-	-	-	+	+	+
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	-	-	-	+	+	+
NasalCrom Nasal Spray	Cromolyn	15% v/v	-	-	-	+	+	+
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	-	-	-	+	+	+
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	-	-	-	+	+	+
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	-	-	-	+	+	+
Antibiotic	Mupirocin	10 mg/mL	-	-	-	+	+	+
Tamiflu	Oseltamivir Phosphate	5 mg/mL	-	-	-	+	+	+
Antibiotic	Tobramycin	4 ug/mL	-	-	-	+	+	+

Conclusion:

Based on the data generated by this study, the endogenous interfering substances tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen test.

3.5 Cross Reactivity (Analytical Specificity)

To demonstrate the related pathogens and organisms that are reasonably likely to be present in the nasal cavity do not interfere with test performance of Flow*flex* SARS-Cov-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#2:202009001
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure: Cross-Reactivity Wet Testing

Samples were prepared by spiking each stock inactivated viruses and bacteria into the pooled human negative clinical matrix. Each organism and virus were tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test.

Test Results:

No cross-reactivity was observed with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Cross-Reactive Results		
Virus	Adenovirus	1.14×10^6 $TCID_{50}$/mL	-	-	-
	Enterovirus	9.50×10^5 $TCID_{50}$/mL	-	-	-
	Human coronavirus 229E	1.04×10^5 $TCID_{50}$/mL	-	-	-
	Human coronavirus OC43	2.63×10^5 $TCID_{50}$/mL	-	-	-
	Human coronavirus NL63	1.0×10^5 TCID50/mL	-	-	-
	Human Metapneumovirus	1.25×10^5 $TCID_{50}$/mL	-	-	-
	MERS-coronavirus	7.90×10^5 $TCID_{50}$/mL	-	-	-

	Influenza A	1.04 x 10^5 $TCID_{50}$/mL	-	-	-
	Influenza B	1.04 x 10^5 $TCID_{50}$/mL	-	-	-
	Parainfluenza virus 1	1.25 x 10^5 $TCID_{50}$/mL	-	-	-
	Parainfluenza virus 2	3.78 x 10^5 $TCID_{50}$/mL	-	-	-
	Parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL	-	-	-
	Parainfluenza virus 4	2.88 x 10^6 $TCID_{50}$/mL	-	-	-
	Respiratory syncytial virus	3.15 x 10^5 $TCID_{50}$/mL	-	-	-
	Rhinovirus	3.15 x 10^5 $TCID_{50}$/mL	-	-	-
Bacteria	Bordetella pertussis	2.83 x 10^9 CFU/mL	-	-	-
	Chlamydia trachomatis	3.13 x 10^8 CFU/mL	-	-	-
	Haemophilus influenza	1.36 x 10^8 CFU/mL	-	-	-
	Legionella pneumophila	4.08 x 10^9 CFU/mL	-	-	-
	Mycobacterium tuberculosis	1.72 x 10^7 CFU/mL	-	-	-
	Mycoplasma pneumoniae	7.90 x 10^7 CFU/mL	-	-	-
	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	-	-	-
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	-	-	-
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	-	-	-
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	-	-	-
	Pseudomonas aeruginosa	1.87 x 10^8 CFU/mL	-	-	-
	Pooled human nasal wash	N/A	-	-	-
Yeast	Candida albicans	1.57 x 10^8 CFU/mL	-	-	-

3.6 Microbial Interference Studies

To demonstrate that false negatives will not occur with Flow*flex* SARS-Cov-2 Antigen Test when SARS-CoV-2 is present in a specimen with other microorganisms.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure:

The samples were prepared by spiking each inactivated viruses and bacterial cells and heat inactivated SARS-CoV-2 virus into the pooled human negative clinical matrix. Each organism and virus in the presence of heat inactivated SARS-CoV-2 virus at 9.71 x 10^2 TCID50/mL were tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Test.

Test Results:

No interference was observed in the presence of heat inactivated SARS-CoV-2 virus with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Interference Results		
Virus	Adenovirus	1.14 x 10^6 $TCID_{50}$/mL	+	+	+
	Enterovirus	9.50 x 10^5 $TCID_{50}$/mL	+	+	+
	Human coronavirus 229E	1.04 x 10^5 $TCID_{50}$/mL	+	+	+
	Human coronavirus OC43	2.63 x 10^5 $TCID_{50}$/mL	+	+	+
	Human coronavirus NL63	1.0 x 10^5 TCID50/mL	+	+	+
	Human Metapneumovirus	1.25 x 10^5 $TCID_{50}$/mL	+	+	+
	MERS-coronavirus	7.90 x 10^5 $TCID_{50}$/mL	+	+	+

	Influenza A	1.04×10^5 $TCID_{50}$/mL	+	+	+
	Influenza B	1.04×10^5 $TCID_{50}$/mL	+	+	+
	Parainfluenza virus 1	1.25×10^5 $TCID_{50}$/mL	+	+	+
	Parainfluenza virus 2	3.78×10^5 $TCID_{50}$/mL	+	+	+
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	+	+	+
	Parainfluenza virus 4	2.88×10^6 $TCID_{50}$/mL	+	+	+
	Respiratory syncytial virus	3.15×10^5 $TCID_{50}$/mL	+	+	+
	Rhinovirus	3.15×10^5 $TCID_{50}$/mL	+	+	+
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	+	+	+
	Chlamydia trachomatis	3.13×10^8 CFU/mL	+	+	+
	Haemophilus influenza	1.36×10^8 CFU/mL	+	+	+
	Legionella pneumophila	4.08×10^9 CFU/mL	+	+	+
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	+	+	+
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	+	+	+
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	+	+	+
	Streptococcus pneumoniae	1.04×10^8 CFU/mL	+	+	+
	Streptococcus pyogenes	4.10×10^6 CFU/mL	+	+	+
	Pneumocystis jirovecii-S. cerevisiae	8.63×10^7 CFU/mL	+	+	+
	Pseudomonas aeruginosa	1.87×10^8 CFU/mL	+	+	+
	Pooled human nasal wash	N/A	+	+	+
Yeast	Candida albicans	1.57×10^8 CFU/mL	+	+	+

Conclusion:

Based on the data generated by this study, the organisms or viruses tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen test.

3.7 Hook effect

To evaluate if the false negative result can be observed when test very high levels of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-Cov-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure:

Samples were prepared by adding heat inactivated SARS CoV-2 virus into the human negative nasal matrix pool for preparing the highest concentration 7.5 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 available in the human negative nasal matrix. Contrived nasal swab samples were prepared by absorbing 50 uL of the virus at 7.5 x 10^5 TCID50/mL onto the swab. The contrived swab samples were tested in triplicate according to the package insert.

Conclusion:

No high dose hook effect was observed when tested with up to a concentration of 7.5 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-CoV-2 Antigen Test.

3.8 Read Time Flex

To demonstrate that the test result is stable when read within the recommended time window.

Material:

SARS-CoV-2 Antigen Rapid Test, Lot#1:COV0110005
Buffer, Lot#:TDE20110009
SARS-CoV-2 Antigen Negative Sample Lot#: 20201104
SARS-CoV-2 Antigen Low Positive Control Lot#: COVAG200930L
SARS-CoV-2 Antigen Middle Positive Control Lot#: COVAG200930M
ACON Rapid Flow Test Color Card, Lot#20200112

Procedure:

SARS-CoV-2 Antigen negative, high, middle and low positive sample are 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 and 30 mins.

Test results:

SARS-CoV-2 Samples	5 min	10 min	15 min	20 min	30 min
Neg	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates
Low Pos	- / 3 replicates	+/ 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
Mid Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
High Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates

Conclusion:

The results are stable when read between 10 minutes to 30 minutes.

3.9 Stability Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1
- SARS-CoV-2 Antigen positive control swab, Lot#1: 202009003P-1, Lot#2: 202009003P-2, Lot#3: 202009003P-3
- SARS-CoV-2 Antigen negative control swab, Lot#1: 202009003N-1, Lot#2: 202009003N-2, Lot#3: 202009003N-3

3.9.1 Accelerated stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the accelerate stability study.

Procedure:

Accelerated stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 55°C/65°C to estimate product stability. Tests will be assayed according to package insert at designated time points. For each device lot, run 3 replicates per sample at each time points. Read the results according to package insert.

Test results:

Result of SARS-CoV-2 Antigen Rapid Test

55°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

65°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

Result of SARS-CoV-2 Antigen Control swab:

55°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

65°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

Conclusion:

SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swabs are stable at 65°C for 14 days, so the shelf life can be estimated at least 24 months.

3.9.2 Real time stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the real time stability study.

Procedure:

Real time stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 2-8°C/30°C to estimate product stability. Tests will be assayed according to package insert at designated time points every 3 months until the timepoints that performance does not meet the acceptance criteria. For each device lot, negative and different levels of positive samples will be tested, run 3 replicates per sample at each time points. Read the results according to package insert.

Acceptance criteria:

Negative sample will generate negative result

Low positive, medium positive and high positive sample will generate positive results

Test results:

Result of SARS-CoV-2 Antigen Rapid Test:

2-8°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				
6 months				
9 months				
12 months				

30°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				

6 months				
9 months				
12 months				

Result of SARS-CoV-2 Antigen Control swab:

2-8°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

30°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

Conclusion:

The real time stability of SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swab are still in process. It is scheduled to finish in December 2022.

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany