SGTi-flex COVID-19 Ag

REF CAGT001E0, CAGT002E0, CAGT005E0
CAGT010E0, CAGT025E0, CAGT025E1

IVD

▶ INTENDED USE

SGTi-flex COVID-19 Ag is a lateral flow immunoassay for qualitative detection of Nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal and nasal swab specimens directly collected or collected in Copan Universal Transport Medium (UTM-RT), BD universal viral transport (UVT) system, Noble Biosciences Clinical Virus Transport Medium (CTM), Centers for Disease Control and prevention viral transport medium (VTM, SOP#: DSR-052-05) from asymptomatic individuals or who are suspected of COIVD-19 by their healthcare provider within the first 5 days after symptom onset. The test is used as an aid in the rapid diagnosis of SARS-CoV-2 viral infections.
The SGTi-flex COVID-19 Ag is intended for use by trained laboratory personnel or healthcare professionals.
For laboratory use or for Point of Care testing.
This assay is not intended for home testing (or self-testing).
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. Laboratories are required to report all positive results to the appropriate public health authorities.
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, and confirmed with a molecular assay, if necessary for patient management.
The test is intended for serial testing of symptomatic individuals (within the first 5 days after symptom onset) for use at least twice with 48 hours between tests, or for serial testing of asymptomatic individuals for use at least three times with 48 hours between tests.

▶ SUMMARY AND EXPLANATION

The novel coronavirus (SARS-CoV-2) was identified in December 2019, and in February 2020, the World Health Organization (WHO) officially named the disease caused by SARS-CoV-2 as COVID-19 (Coronavirus Disease 2019). Belonging to the family Coronaviridae, it has a positive-sense single-stranded RNA and can be transmitted between people. The coronaviruses identified for human infection include 229E, NL63 belonging to α-Coronaviruses and HKU1, OC43, SARS-CoV, MERS-CoV belonging to β-Coronaviruses.
The new coronavirus was published under the name of SARS-CoV-2, with 80% of genetic similarity to SARS-CoV by ICTV (International Committee on Taxonomy of Viruses).
COVID-19 spreads mainly through respiratory droplets, which cause lethargy, fever, dry cough, and dyspnea when infected. It can be even led to death with its severe symptoms like sepsis, MOF (Multiple Organ Failure) and ARDS (Acute Respiratory Distress Syndrome). It is more contagious than SARS which caused more than 800 deaths and 8,000 infected patients. Moreover, it has an incubation period of about 3 days to up to 16 days and becomes a big threat as infectivity appears even during the incubation period. There is currently no specific treatment for COVID-19, and rapid and accurate diagnosis is an important issue for isolation of patients with symptoms of suspected COVID-19.

▶ PRINCIPLE

SGTi-flex COVID-19 Ag is an immunoassay for qualitative detection of SARS-CoV-2 antigens from nasopharyngeal and nasal swab specimens. The SARS-CoV-2 antigens are extracted from swab in the extraction buffer and the extracted sample solutions are loaded to the sample well of the Test Cassette. When the sample is loaded, the detection antibody binds to SARS-CoV-2 antigen and flows through the membrane. The detection antibody-gold conjugate and SARS-CoV-2 antigen move to the test line area and are accumulated by the capture antibody immobilized on the membrane. This leads to the generation of a reddish colored band. The intensity of the band depends on quantity of SARS-CoV-2 antigen and the test results are interpreted by user's eye according to the instructions for use.

▶ MATERIALS SUPPLIED

	CAGT001E0	CAGT002E0
✓ Test Cassette	1 EA	2 EA
✓ Extraction Buffer	1 EA (0.3 mL/tube)	2 EA (0.3 mL/tube)
✓ Dropping cap	1 EA	2 EA
✓ Sample collection swab*	1 EA	2 EA
✓ Instructions for Use	1 EA	1 EA

	CAGT005E0	CAGT010E0
✓ Test Cassette	5 EA	10 EA
✓ Extraction Buffer	5 EA (0.3 mL/tube)	10 EA (0.3 mL/tube)

✓ Dropping cap	5 EA	10 EA
✓ Sample collection swab*	5 EA	10 EA
✓ Instructions for Use	1 EA	1 EA

	CAGT025E0	CAGT025E1
✓ Test Cassette	25 EA	25 EA
✓ Extraction Buffer	25 EA (0.3 mL/tube)	1 EA (10 mL/Bottle)
✓ Extraction Tube	-	25 EA
✓ Dropping cap	25 EA	25 EA
✓ Sample collection swab*	25 EA	25 EA
✓ Instructions for Use	1 EA	1 EA

** Sample collection swab*
- Nasopharyngeal & Nasal swab (MFS96000BQ)

▶ STORAGE AND STABILITY

- Store SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer at 5~25°C (41~77°F).
- If SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer are stored in cold storage, allow them for 30 minutes to return to room temperature before testing.
- Do not open the pouch of Test Cassette until ready to use. After opening aluminum pouch, Test Cassette should be used immediately.
- Keep away from direct sunlight.

▶ WARNING AND PRECAUTIONS

- ✓ For *in vitro* diagnostic use only.
- ✓ This test is intended for assessment of coronavirus infection by detecting SARS-CoV-2 antigen, but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other methods and clinical information (signs and symptoms) should be used and considered for diagnosis.
- ✓ Please read the instructions carefully before you begin the test and follow the procedure correctly.
- ✓ It is prohibited to reuse Test Cassettes because they are single use only.
- ✓ The test result after the expiry date is not reliable.
- ✓ Test Cassette is sensitive to moisture and should be stored in a sealed pouch until use. Use Test Cassette immediately after opening the pouch.
- ✓ Do not use the Test Cassette if it is broken or the pouch is not stored in sealed.
- ✓ Samples and Test Cassette must be at room temperature before testing.
- ✓ It is an *in vitro* diagnostic product and the risk of infection is low because there is no direct contact with the human body. However please be cautious when handling Test Cassette and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples and Test Cassettes properly in accordance with the relevant regulations.
- ✓ Smoking and eating are prohibited at test site when handing specimens or kit reagents.

▶ TEST PREPARATION

1. Test should be done immediately after sample collecting.

(1) If sample swabs are not used immediately after sample collection, specimen is recommended to be stored in deep freezer at -70˚C (or in dry ice or liquid nitrogen). A freezer at -20˚C is NOT recommended. If the specimen is stored at 2-8 ℃, it can be stored up to 72 hours.

2. Preparation before Test

(1) In case the samples and reagents were refrigerated, keep them ambient for 15~30 minutes to let it reach the room temperature.

(2) Test Cassette is moisture sensitive so should be used **immediately** after opening.

▶ SAMPLE COLLECTION

SGTi-flex COVID-19 Ag can be performed with nasopharyngeal swab and nasal swab.

1. For CAGT025E1, dispense 300 µL (fill-line) of Extraction Buffer into the Extraction Tube.
2. For CAGT001E0, CAGT002E0, CAGT005E0, CAGT010E0 and CAGT025E0, remove the sealing foil from the Extraction Buffer tube.
3. Place the Extraction Tube in the tube rack.
4. SGTi-flex COVID-19 Ag uses the sample of nasopharyngeal swab and nasal swab.

(1) Direct Swab

1) Please use single use sample collecting swab.

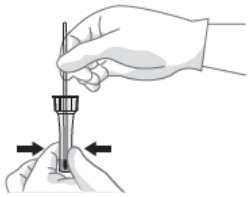
2) For nasal swab, using a collection swab provided in kit, carefully insert the entire absorption tip of the swab (usually 1/2 to 3/4 of an inch (1 to 1.5 cm)) inside the nostril and firmly sample the nasal wall at least 4 times. Take approximately 15 seconds to collect the sample. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostril with same swab. And slowly remove swab while rotating it.

<nasopharyngeal swab> <nasal swab>

3) For nasopharyngeal swab, insert a nasopharyngeal swab into the nostril, swab over the surface of the posterior nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to adsorb secretions. And slowly remove swab while rotating it.

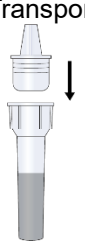
4) Place the sample collecting swab into the Extraction Buffer tube containing 300 µL extraction buffer and rotate it more than 5 times to allow extraction.

5) Take the sample collecting swab out by pressing and squeezing the sides of the tube to extract the remaining liquid from the swab. Used swab is classified as infectious waste and dispose of used swab properly in accordance with the relevant regulations.



6) Press the Dropping Cap onto the Extraction Buffer tube containing the processed sample.

(2) Swab in Viral Transport Media (VTM)

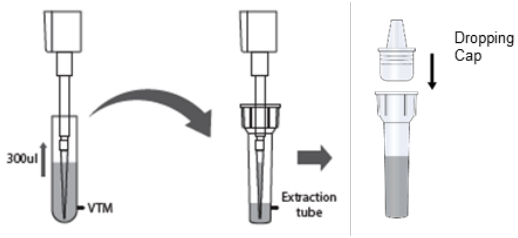


NOTE: Only Copan Universal Transport Medium(UTM-RT), Noble Biosciences Clinical Virus Transport Medium(CTM), and BD universal transport media (UVT) and CDC VTM formula(SOP-DSR-052-05) have been validated with the assay.

1) Mix the specimen in VTM by vortexing.

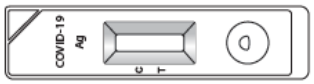
2) Using micro pipette, transfer 300 µL of sample in VTM to the sample extraction buffer tube.

3) Press the Dropping Cap onto the Extraction Buffer tube containing the processed sample.

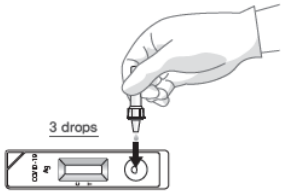


▶ TEST PROCEDURE

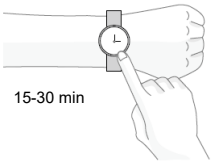
1. Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.



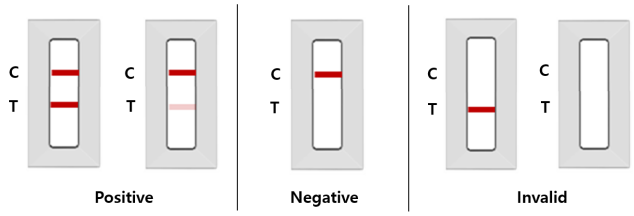
2. Invert the Extraction Buffer tube and add **3 drops** of processed sample into the sample well on the Test Cassette.



3. Read the results in 15 minutes after dispensing the sample. Some positive results may appear faster right after the reaction. The result after 30 minutes is invalid.



[Interpretation of Results]



1. Positive : Test line (T) and Control line (C) are appeared in the result window: Positive for SARS-CoV-2 antigen

   Repeat testing does not need to be performed if the

patient has a positive result at any time.

2. Negative : If only Control line (C) appears in the result window: Negative for SARS-CoV-2 antigen

   To increase the chance that the negative result for COVID-19 is accurate, you should:
   - ✓ Test again in 48 hours if the individual has symptoms on the first day of testing.
   - ✓ Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

   A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen test compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.
   All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

3. Invalid : If control line fails to appear, the result is invalid and retest with a new Test Cassette.

4. Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

[Quality Control]

1. A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

2. Quality Control materials (positive control swab and negative control swab) can be purchased separately.

▶ LIMITATIONS OF THE SYSTEM

1. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other virus or pathogens.
2. The test is a qualitative test for detection of SARS-CoV-2 antigen in human nasopharyngeal and nasal swab specimens and does not provide the quantitative value of viral load in the specimen.
3. The test is for *in vitro* diagnostic use only.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. SARS-CoV may cause positive results. SARS-CoV can be detected as a cross reaction.
6. The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern except Delta (B.1.617.2), omicron (B.1.1.529), B.1.1.7, B.1.351, P.1, B.1.617.2, B.1.1.529, BA.4, BA.5, BQ.1, and XBB.1.
7. The performance of this device has not been assessed in a population vaccinated against COVID-19.
8. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

▶ Serial Testing (Repeat Testing) Information and Limitations

1. Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
2. A negative result should be followed up with repeat,

or serial testing at least twice over three days with at least 48 hours between tests for symptomatic individuals and/or at least three times over five days with at least 48 hours between tests for asymptomatic individuals. A self-test may be used for this additional testing.

3. The performance of this test was not clinically validated for serial testing. Serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
4. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

▶ PERFORMANCE CHARACTERISTICS

1. **Limit of Detection (LoD)**
   - The sensitivity using direct swab is 3.5 $x10^2$ $TCID_{50}$/mL based on Gamma Irradiated SARS-CoV-2 (BEI Resources, NR-52287, USA-WA1/2020).
   - The sensitivity using swab in viral transport media is 2.8 $x10^3$ $TCID_{50}$/mL based on Gamma Irradiated SARS-CoV-2 (BEI Resources, NR-52287, USA-WA1/2020).

2. Cross-Reactivity

SGTi-flex COVID-19 Ag was evaluated with 20 other virus and 13 bacteria. The results show that the SGTi-flex COVID-19 Ag has no cross-reactivity with samples containing tested viruses and bacteria except on SARS -CoV. The results showed no microbial interference with the organisms at the concentrations tested.

Table 1. Virus

	Strain	Cross-reactivity	Interference
		Results	Results
1	Alpha Coronavirus (229E)	Negative	Positive
2	Beta Coronavirus OC43	Negative	Positive
3	Human Coronavirus NL63	Negative	Positive
4	Beta Coronavirus (MERS)	Negative	Positive
5	Beta Coronavirus (SARS-CoV)	Positive	Positive
6	Adenovirus type 5	Negative	Positive
7	Human Metapneumovirus	Negative	Positive
8	Parainfluenza Virus serotype 1	Negative	Positive
9	Parainfluenza Virus serotype 2	Negative	Positive
10	Parainfluenza Virus serotype 3	Negative	Positive
11	Parainfluenza Virus serotype 4	Negative	Positive
12	Influenza A/H1N1	Negative	Positive
13	Influenza A/H3N2	Negative	Positive
14	Influenza A/H5N1	Negative	Positive
15	Influenza B	Negative	Positive
16	Respiratory Syncytial virus type A	Negative	Positive
17	Respiratory Syncytial virus type B	Negative	Positive
18	Rhinovirus group A	Negative	Positive
19	Enterovirus 68	Negative	Positive
20	Human Corona virus HKU1	*In Silico*	-

Table 2. Bacteria

	Strain	Cross-reactivity	Interference
		Results	Results
1	*Hemophilus influenzae*	Negative	Positive
2	*Streptococcus Pneumoniae*	Negative	Positive
3	*Candida albicans*	Negative	Positive
4	Pooled human nasal fluid	Negative	Positive
5	*Bordetella pertussis*	Negative	Positive
6	*Mycoplasma pneumoniae*	Negative	Positive
7	*Chlamydophila pneumoniae*	Negative	Positive
8	*Legionella pneumophila*	Negative	Positive
9	*Staphylococcus epidermidis strain*	Negative	Positive
10	*Mycobacterium tuberculosis*	Negative	Positive
11	*Pneumocystis jirovecii*	Negative	Positive
12	*Streptococcus pyogenes*	Negative	Positive
13	*Staphylococcus aureus*	Negative	Positive

3. Analytical Specificity – Interference test

Various concentrations of potential interfering substances were prepared in negative and positive sample. The results show that the SGTi-flex COVID-19 Ag has no interference by the potential interfering substances below which may exist in specimen, such

as drugs, and chemical and biological analytes.

Table 3. Interfering substances

No	Interfering substance	Concentration
1	Albumin	50 mg/ml
2	Glucose	1.2 mg/ml
3	Hemoglobin	4 mg/ml
4	Bilirubin	5 mg/ml
5	mucin	1.0 %
6	Whole blood	4.0 %
7	Phenylephrine hydrochloride	10 mg/ml
8	Dexamethasone	0.6 mg/ml
9	Flunisolide	2.5 mg/ml
10	Budesonide	1 mg/ml
11	Benzocaine	5 mg/ml
12	Menthol	40 mg/ml
13	Zanamivir	10 mg/ml
14	Tobramycin	20 mg/ml
15	Tamiflu (Oseltamivir)	6 mg/ml
16	Acetaminophen	10 mg/ml
17	Ibuprofen	5 mg/ml
18	Aspirin	2 mg/mL
19	Naso GEL	5% v/v
20	Oxymetazoline	0.1 mg/mL
21	Cromolyn	0.03 mg/mL
22	Zicam	5% v/v
23	Alkalol	10% v/v
24	Mupirocin	10 mg/mL
25	Fluticasone Propionate	5% v/v
26	Sore Throat Phenol Spray	15% v/v
27	Heparin sodium salt	3000 U/L

4. High-dose Hook Effect

There is no hook effect was observed at high levels of Gamma Irradiated SARS-CoV-2 (BEI Resources, NR-52287, USA-WA1/2020) up to 2.8 x10^6 $TCID_{50}$/mL.

5. Precision test

Within-run, Between-run, Batch-to-batch, Day-to-day, and Between site performance results meet 100% of the acceptance criteria.

6. Clinical Agreement Study

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

[Clinical Evaluation 1]

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 320 specimens including 23 asymptomatic patient specimens.

The results for nasopharyngeal swab showed the overall percent was 97.27%. The positive and negative agreements was 91.67% and 99.38%, respectively.

[Total Clinical Performance for nasopharyngeal swab]

		Real time RT-PCR (NP swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (NP Swab)	Positive	55	1	56
	Negative	5	159	164
	Total	60	160	220

(1) Overall percent agreement(OPA): 97.27%
(95% CI: 94.18%~98.74%)
(2) Positive percent agreement(PPA): 91.67%
(95% CI: 81.93%~96.39%)
(3) Negative percent agreement(NPA): 99.38%
(95% CI: 96.55%~99.89%)

The results for 100 nasal swabs including 25 asymptomatic patient specimens showed the overall percent was 93.00%. The positive and negative agreements was 88.33% and 100.00%, respectively.

[Total Clinical Performance for nasal swab]

		Real time RT-PCR (NP swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (Nasal swab)	Positive	53	0	53
	Negative	7	40	47
	Total	60	40	100

(1) Overall percent agreement(OPA): 93.00%
(95% CI: 86.25%~96.57%)
(2) Positive percent agreement(PPA): 88.33%
(95% CI: 77.82%~94.23%)
(3) Negative percent agreement(NPA): 100.00%
(95% CI: 91.24%~100.00%)

[Clinical Evaluation 2]

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 140 specimens including 30 asymptomatic patient specimens.

The results for nasopharyngeal swab showed the overall percent was 93.57%. The positive and negative agreements was 88.75% and 100.00%, respectively.

[Total Clinical Performance for nasopharyngeal swab]

		Real Time RT-PCR (NP swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (NP swab)	Positive	71	0	71
	Negative	9	60	69
	Total	80	60	140

(1) Overall percent agreement (OPA): 93.57%
(95% CI: 88.23%~96.58%)
(2) Positive percent agreement (PPA): 88.75%
(95% CI: 79.98%~93.97%)
(3) Negative percent agreement (NPA): 100.00%
(95% CI: 93.98%~100.00%)

[Clinical Evaluation 3]

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 276 specimens including 10 asymptomatic patient specimens.

The results for nasal swab showed the overall percent was 96.74%. The positive and negative agreements was 94.12% and 99.29%, respectively.

[Total Clinical Performance for nasal swab]

		Real time RT-PCR (NP swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (Nasal swab)	Positive	128	1	129
	Negative	8	139	147
	Total	136	140	276

(1) Overall percent agreement(OPA): 96.74%
(95% CI: 93.92%~98.28%)
(2) Positive percent agreement(PPA): 94.12%
(95% CI: 88.82%~96.99%)
(3) Negative percent agreement(NPA): 99.29%
(95% CI: 96.07%~99.87%)

[Asymptomatic Patients Evaluation]

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted using 43 direct nasal and 60 direct NP swabs from SARS-CoV-2 asymptomatic patients including 10% low positive (8 specimens, >30 Ct Value) specimen.

The results for asymptomatic showed an overall percent agreement of 92.23% (95% CI: 85.42~96.01%). The total positive agreements(PPA) was 89.04% (95% CI: 79.84~94.34%), while the total negative agreements(NPA) was 100.00% (95% CI: 88.65~100.00%).

PPA and NPA by specimen type are as follows.

		Real Time RT-PCR (NP swab)	
		Positive	Negative
SGTi-flex COVID-19 Ag (NP swab)	Positive	36	0
	Negative	4	20
	Total	40	20
PPA (95% CI)		90.00% (76.95~96.04%)	
NPA (95% CI)		100.00% (83.89~100.00%)	

		Real Time RT-PCR (NP swab)	
		Positive	Negative
SGTi-flex COVID-19 Ag (Nasal swab)	Positive	29	0
	Negative	4	10
	Total	33	10
PPA (95% CI)		87.88% (72.67~95.18%)	
NPA (95% CI)		100.00% (72.25~100.00%)	

7. Point of Care Studies

[Study 1]

The Point of Care (POC) study for SGTi-flex COVID-19 Ag was conducted by 9 non-laboratorian operators for a total of 70 specimens.
As the result of the POC study, the overall percent agreement was 95.71%. The positive and negative agreements were 92.50% and 100.00%, respectively.

[Performance analysis in POC settings]

		Real time RT-PCR (NP swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (NP swab)	Positive	37	0	37
	Negative	3	30	33
	Total	40	30	70

(1) Overall percent agreement(OPA): 95.71%
(95% CI: 88.14%~98.53%)
(2) Positive percent agreement(PPA): 92.50%
(95% CI: 80.14%~97.42%)
(3) Negative percent agreement(NPA): 100.00%
(95% CI: 88.65%~100.00%)

[Study 2]

The Point of Care (POC) study for SGTi-flex COVID-19 Ag was conducted by 6 non-laboratorian operators at 2 sites for 114 direct nasal swab specimens collected prospectively.
As the result of the POC study, the overall percent agreement was 96.49%. The positive and negative

agreements were 90.00% and 100.00%, respectively.

[Performance analysis in POC settings]

		Real Time RT-PCR (NP Swab)		
		Positive	Negative	Total
SGTi-flex COVID-19 Ag (Nasal swab)	Positive	36	0	36
	Negative	4	74	78
	Total	40	74	114

(1) Overall percent agreement(OPA): 96.49%
(95% CI: 91.32%~98.63%)
(2) Positive percent agreement(PPA): 90.00%
(95% CI: 76.95%~96.04%)
(3) Negative percent agreement(NPA): 100.00%
(95% CI: 95.06%~100.00%)

Prospective positive samples with Ct value ≤20 has a positive percent agreement (PPA) of 100% (n=15) and Ct value >30 has a positive percent agreement (PPA) of 25.00% (n=4).

Two Studies demonstrated that non-laboratory personnel can perform the test accurately at near patient or POC testing environment.

The robustness of SGTi-flex COVID-19 Ag for use in near patient or Point of Care (POC) testing was demonstrated by five (reading time, processed sample volume, temperature, humidity, light source) Flex studies.

8. Serial-Testing Clinical Performance

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARSCoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table 4.

Table 4. Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

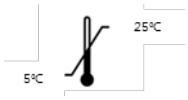
Days after first PCR positive test results	Asymptomatic on first day of testing			Symptomatic on first day of testing		
	Ag Positive/ PCR positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performed an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

▶ REFERENCES

1. WHO, Coronavirus disease 2019 (COVID-19) Situation report
2. J.virol. Methods. 2008, 152(1-2): 77-84, A rapid point of care immunoswab assay for SARS-CoV detection

▶ EXPLANATION OF SYMBOLS USED ON PACKAGE

IVD	*In vitro* diagnostic medical device
Σ n	Contains sufficient for n tests
	Do not reuse
	Consult instructions for use.
	Store between 5°C and 25°C
	Caution, consult accompanying documents
LOT	Batch code
	Use by
REF	Catalogue number
	Manufacturer

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