SGTi-flex

COVID-19 Ag

IVD REF CAGT025E1 CE

INTENDED USE

SGTi-flex COVID-19 Ag is an immunoassay for qualitative detection of SARS-CoV-2 antigens directly from nasopharyngeal and oropharyngeal swab specimens. The test is used as an aid in the rapid diagnosis of SARS- CoV-2 viral infections.

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 directly from nasopharyngeal and oropharyngeal 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

- Test Cassette ····· 25
- Extraction Buffer ····· 1 (10 mL/Bottle)
- Extraction Tube ····· 25
- Dropping cap ····· 25
- Sample collection swab ····· 25
- Instructions for Use ····· 1

STORAGE AND STABILITY

- Store SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer at 2~30°C (36~86°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.
- Clinical diagnosis through this product should be made through a comprehensive review of the specialist based on other test methods and clinical symptoms.
- 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°C, it can be stored up to 72 hours.

2. Preparation before Test

1) All samples and reagents should be stored at room temperature and stayed homogenous 15~30 minutes prior to testing.

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

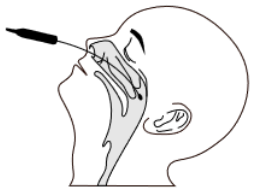
SAMPLE COLLECTION

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

1. SGTi-flex COVID-19 Ag uses the sample of nasopharyngeal swab and oropharyngeal swab.

1) Please use single use sample collecting swab.

2) Insert a nasopharyngeal swab into the nostril of the patient, swab over the surface of the posterior nasopharynx.
Swab should reach depth equal to distance from nostrils to outer opening of the ear .



<nasopharyngeal swab>

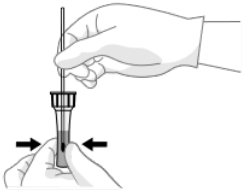
※ *The sample collection swab provided by SGTi-flex COVID-19 Ag is used for nasopharyngeal swab.*

3) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. And slowly remove swab while rotating it.

4) Dispense the extraction buffer by dividing each 300 µL into an Extraction Tube.

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

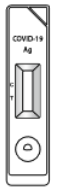
6) Take the sample collecting swab out by pressing and squeezing the sides of the tube to extract the remaining liquid from the swab. Used swab is classified as infectious waste and dispose of used swab properly in accordance with the relevant regulations.



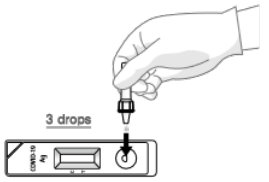
7) Press the Dropping Cap onto the Extraction Tube containing the processed sample.

TEST PROCEDURE

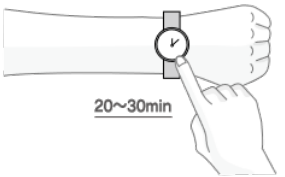
1. Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.



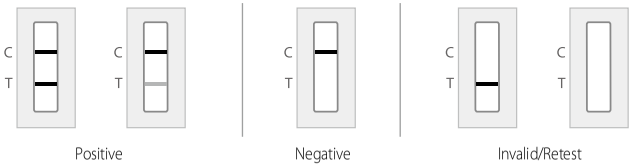
2. Invert the Extraction Buffer tube and add 3 drops of processed sample (Approximately 85 µL) into the sample well on the Test Cassette.



3. Read the results in 20~30 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

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

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

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. The test is for qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal and oropharyngeal swab and it does not indicate the quantification of the virus.
2. The test is for *in vitro* diagnostic use only.
3. 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.
4. SARS-CoV may cause positive results. SARS-CoV can be detected as a cross reaction.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection : (LoD) :

The study used heat inactivated viral culture fluid of SARS-CoV-2 isolated USA-WA1/2020. The LOD is 5.3 x10^2 $TCID_{50}$/mL.

2. Cross-Reactivity

SGTi-flex COVID-19 Ag was evaluated with 21 other virus and 12 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.

Table 1. Virus

No	Strain	Results
1	Alpha Coronavirus (229E)	Negative
2	Beta Coronavirus (MERS) NP protein	Negative
3	Beta Coronavirus (SARS-CoV) NP protein	Positive
4	Beta Coronavirus OC43	Negative
5	Influenza A/H1N1 A/Brisbane/02/2018 (H1N1)pdm09-like virus (13/234)	Negative
6	Influenza A/H3N2 Influenza Antigen A/New Caledonia/71/2014 (H3N2, 15/238)	Negative
7	Influenza A/H5N1 Influenza Antigen A/Anhui/1/05 (H5N1, 07/290)	Negative
8	Influenza B Influenza Antigen B/Guangdong/120/2000 (01/546)	Negative
9	Epstein-Barr Virus	Negative
10	Rhinovirus group A	Negative
11	Respiratory Syncytial virus type A	Negative
12	Respiratory Syncytial virus type B	Negative
13	Mumps Virus	Negative
14	Adenovirus type 5	Negative
15	Human Coxsackie B4	Negative
16	Human Meta pneumovirus	Negative
17	Human Measles Mvi/Moscow Rus/1988 Genotype A	Negative
18	Parainfluenza Virus serotype 1	Negative
19	Parainfluenza Virus serotype 2	Negative
20	Parainfluenza Virus serotype 3	Negative
21	Parainfluenza Virus serotype 4	Negative

Table 2. Bacteria

No	Strain	Results
1	Group A streptococcus antigen	Negative
2	Group B streptococcus antigen	Negative
3	Streptococcus Pneumoniae antigen	Negative
4	Escherichia coli culture	Negative
5	Corynebacterium glutamicum culture	Negative
6	Lactobacillus plantarum culture	Negative
7	Legionella spp culture	Negative
8	Pseudomonas aeruginosa culture	Negative
9	Staphylococcus epidermidis culture	Negative
10	Mycobacterium tuberculosis	Negative
11	Hemophilus influenzae	Negative
12	Streptococcus spp	Negative

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 prescription/OTC drugs, and elevated levels of chemical and biological analytes.

Table 3. Interfering substances

No.	Interfering substance	Concentration	No.	Interfering substance	Concentration
1	Albumin	50 mg/mL	10	Menthol	40 mg/mL
2	Glucose	1.2 mg/mL	11	Zanamivir	10 mg/mL
3	Hemoglobin	4 mg/mL	12	Tobramycin	20 mg/mL
4	Bilirubin	5 mg/mL	13	Tamiflu (Oseltamivir)	6 mg/mL
5	Phenylephrine hydrochloride	10 mg/mL	14	mucin	1.0 %
6	Dexamethasone	0.6 mg/mL	15	Whole blood	1.0 %
7	Flunisolide	2.5 mg/mL	16	Acetaminophen	10 mg/mL
8	Budesonide	1 mg/mL	17	Ibuprofen	5 mg/mL
9	Benzocaine	5 mg/mL	18	Aspirin	2 mg/mL

4. Precision test

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

5. Clinical Agreement Study

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 183 specimens.

The results showed the accuracy (overall percent agreement) was 95.63%. The sensitivity and specificity (positive and negative agreements) were 91.57% and 99.00%, respectively.

		Reference method		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 Ag)	Positive	76	1	77
	Negative	7	99	106
	Total	83	100	183

(1) Accuracy (Overall percent agreement) : 95.63% (175/183, 95% CI: 91.61%~97.77%)

(2) Sensitivity (Positive percent agreement) : 91.57% (76/83, 95% CI: 83.60%~95.85%)

(3) Specificity (Negative percent agreement) : 99.00% (99/100, 95% CI: 94.55%~99.82%)

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 25	Contains sufficient for 25 tests
	Consult instructions for use.	2°C 30°C	Store between 2°C and 30°C
LOT	Batch code		Use by
	Manufacturer	EC REP	Authorized representative in the European community
	Do not reuse	REF	Catalogue number
	Caution, consult accompanying documents	CE	The device conforms to EU-regulations.

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