SGTi-flex

Cat. No. CAGT025E0 **AUSTRALIA**

COVID-19 Ag

IVD REF CAGT900E

INTENDED PURPOSE

SGTi-flex COVID-19 Ag is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus in nasopharyngeal and nasal swab specimen. The test is used as an aid in the rapid diagnosis of SARS- CoV-2 viral infections. This test is intended for use in symptomatic individuals within the first 7 days of symptom onset. The test is intended for use by trained laboratory personnel or healthcare professionals.

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 positivesense 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 lead to death and severe symptoms including 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. The treatments for COVID-19 are evolving, 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 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 test results are interpreted by the user's eyes according to the instructions for use.

MATERIALS SUPPLIED (CAGT025E0)

- Test Cassette ····· 25 EA
- Extraction Buffer ····· 25 (0.3 mL/tube) EA
- Dropping cap ····· 25 EA
- Sample collection swab ····· 25 EA
- Tube Rack ····· 1 EA
- Instructions for Use ····· 1 EA

MATERIALS REQUIRED BUT NOT SUPPLIED

- Timer

STORAGE AND STABILITY

- Store SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer at 2 to 30℃ (36 to 86℉).
- If the SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer are stored in cold storage, allow 30 minutes for them to return to room temperature before testing.
- Do not open the pouch of the Test Cassette until ready to use. After opening the aluminum pouch, the Test Cassette should be used immediately.
- Keep the Test Cassette and the Extraction Buffer away from direct sunlight.
- If sample swabs are not used immediately after sample collection, specimen is recommended to be stored in deep freezer at -70℃.
- If the specimen is stored at 2 to 8℃ (36 to 46℉), it can be stored up to 72 hours.
- Frozen samples can be repeatedly frozen and thawed up to 3 times.
  The specimen was stable up to 4 hours after storage at room temperature.
- The shelf-life of the test kit is 24 months and it is stable until the expiration date marked on the label.

PRINCIPLE

- For *in vitro* diagnostic use only.
- For use only by trained laboratory personnel or healthcare professionals.
- Swab is stored in a sterilized wrapper. Do not use the swab if the wrapper is damaged, torn or not sealed.
- Please read the instructions carefully before you begin the test and follow the procedure correctly.
- Single use only – do not reuse.
- Do not use the test after the expiry date.
- The Test Cassette is sensitive to moisture and should be stored in a sealed pouch until use. Use the Test Cassette immediately after opening the pouch.
- Do not use the Test Cassette if it is broken or if the pouch is not sealed.
- 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 the 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.
- Do not smoke, eat or drink while carrying out the test or while handing specimens or kit reagents.
- Use of gloves is recommended when conducting testing. Eye and skin contact with the Extraction Buffer should be avoided.

TEST PREPARATION

1. Test should be done immediately after sample collection.

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

2. Preparation before Test

1) All samples and reagents should be stored at room temperature for 15 to 30 minutes prior to testing.
2) Test Cassette is moisture sensitive so should be used immediately after opening.

SAMPLE COLLECTION

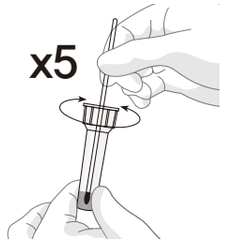
The test can be performed with either a nasopharyngeal swab or a nasal swab.

1. Before sample collection, prepare the Extraction Buffer. Remove the sealing foil from the Extraction Buffer Tube.
2. Place the Extraction Buffer Tube in the tube rack.
3. SGTi-flex COVID-19 Ag can use either a nasopharyngeal swab sample or a nasal swab sample.
   1) Swab is in a sterile wrapper. Please use single use sample collection swab.
   2) For a nasal swab, carefully insert the entire absorption tip of the sample collection 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 nostrils with the same swab. And slowly remove the swab while rotating it.
   3) For a nasopharyngeal swab, insert the sample collection swab into the nostril and swab over the surface of the posterior nasopharynx.
      The swab should reach depth equal to the distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave the swab in place for several seconds to adsorb secretions. And slowly remove the swab while rotating it.

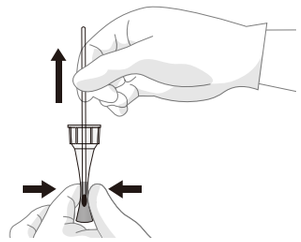
<nasopharyngeal swab> <nasal swab>

※ *The sample collection swab provided by SGTi-flex COVID-19 Ag can be used for either a nasopharyngeal swab or a nasal swab.*

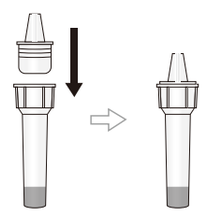
4) Place the sample collection swab into the Extraction Buffer Tube containing 300 µL extraction buffer and rotate it more than 5 times to allow extraction.



5) Take the sample collection swab out by pressing and squeezing the sides of the tube to extract the remaining liquid from the swab.

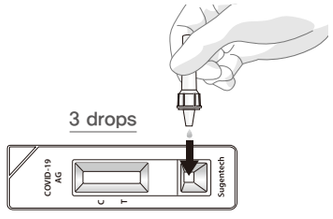


6) Put the Dropping Cap onto the Extraction Buffer Tube. Make sure the Dropping Cap is on tight so that it cannot leak.

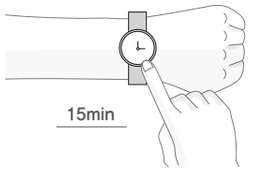


TEST PROCEDURE

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 onto the sample well on the Test Cassette.
   Attention: After each drop is completely absorbed, add the next drop.

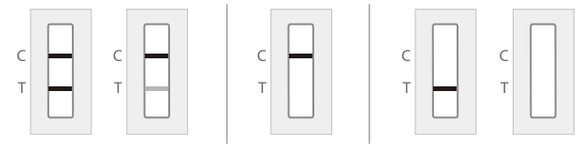


3. Read the results in 15 to 30 minutes after dispensing the sample. Some positive results may appear faster right after the reaction. The result after 30 minutes is invalid.



4. Once you complete the test, put all of the used test kit items into a bag, the seal that bag and dispose of the sealed bag in accordance with local health waste disposal requirements.

INTERPRETATION OF RESULTS



1. Positive : If both a Test line (T) and a Control line (C) appear in the result window, it is a positive result for the SARS-CoV-2 antigen.
If you get a positive result, check local State or Territory guidelines for reporting positive results, and confirmation testing if necessary. If unwell, seek medical assistance.

2. Negative : If only Control line (C) appears in the result window, it is a negative result for the SARS-CoV-2 antigen.
A negative result may not mean you are not infected. Follow the guidance from your local State or Territory Health Department for what to do if a negative result is obtained, and if unwell seek medical assistance.

3. Invalid : If the Control line (C) fails to appear, the result is invalid. You should carry out another test with a new Test Cassette using a freshly collected specimen. If repeated tests also produce invalid results, please report the details to the sponsor.

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. External Quality Control materials can be purchased separately. Please contact sponsor for further information.

SGTi-flex COVID-19 Ag Control (REF: CAGC001E)	
Positive Control swab	1 EA
Negative Control swab	1 EA
Instructions for Use	1 EA

These controls are needed to verify proper test performance consistent with good laboratory practice and are used to particularly under the following circumstances:

- A new operator uses the kit
- A new lot of test kits is used
- A new shipment of kits is used
- To investigate the cause of repeated invalid results

LIMITATIONS OF THE SYSTEM

1. The test is for qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal or nasal 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 and/or if symptoms are present.
4. The separate SARS-CoV virus may cause a positive test result. SARSCoV can be detected by the test as a cross reaction.
5. The test can detect the recombinant nucleocapsid protein of the SARSCoV-2 variants such as Alpha (B 1.1.7), Beta (B.1.351), Gamma (P.1), Kappa (B.1.617.1), B.1.617, Delta (B.1.617.2), B.1.617.3, Epsilon (B.1.427 and B.1.429) and Omicron (B1.1.529). Further clinical testing will be carried out on new variants.
6. The test should be performed within the first 7 days of symptom onset when viral shedding / viral load is highest.
7. If testing is not performed within the first 7 days of symptom onset, false negative results may occur.
8. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
9. A negative result does not rule out infection with another type of respiratory virus.
10. A positive result cannot necessarily determine whether a person is infectious.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD) :

LOD for Original SARS-CoV-2: $3.5x10^2$ $TCID_{50}$/mL ($1.31x10^5$ copies/mL, Ct: 26.68), Delta (B.1.617.2): $5.0x10^2$ $TCID_{50}$/mL ($1.51x10^5$ copies/mL, Ct: 26.13), Omicron (B.1.1.529): $3.75x10^1$ $TCID_{50}$/mL ($2.98x10^5$ copies/mL, Ct: 24.91)

2. Cross-Reactivity

A cross-reactivity evaluation showed that:

- Each of the "Virus" and "Bacteria" listed below were found to have no cross reactivity with SGTi-flex COVID-19 Ag and no impact on the test results of SGTi-flex COVID-19 Ag;
- SARS-CoV-1 (SARS Coronavirus) has cross-reactivity with SGTi-flex COVID-19 Ag and affects the test results of SGTi-flex COVID-19 Ag, because SGTi-flex COVID-19 Ag cannot differentiate between SARSCoV-2 and the SARS-CoV-1 (SARS Coronavirus) due to their high homology;
- Human Coronavirus HKU1 (NP and S Protein) has no cross-reactivity with SGTi-flex COVID-19 Ag and no impact on the test results of SGTiflex COVID-19 Ag when tested using recombinant protein, but crossreactivity cannot be conclusively excluded because the cross-reactivity is not evaluated using the actual virus. Human Coronavirus HKU1 (NP and S Protein) was the only virus tested using recombinant protein; and
- Pneumocystis jirovecii (PJP), which is a type of bacteria, has no crossreactivity with SGTi-flex COVID-19 Ag and no impact on the test results of SGTi-flex COVID-19 Ag when tested in silico. PJP was the only bacteria tested in silico.

Strain (Virus)	Test Conc.	Strain (Virus)	Test Conc.
Alpha Coronavirus (229E)	$8.0x10^5$ $TCID_{50}$/mL	Mumps Virus	$2.85x10^6$ PFU/mL
Beta Coronavirus (MERS)	$4.45x10^5$ $TCID_{50}$/mL	Adenovirus type 5	$3.5x10^{10}$ NIU/mL
Beta Coronavirus (SARS-CoV)	$5.0x10^7$ pfu/mL	Human Coxsackie B	$2.5x10^6$ $TCID_{50}$/mL
Beta Coronavirus (OC43)	8.0×10^4 $TCID_{50}$/mL	Human Metapneumovirus	$5.0x10^5$ $TCID_{50}$/mL
Coronavirus Culture Fluid (NL63)	$6.0x10^4$ $TCID_{50}$/mL	Human Measles virus	$1.4x10^4$ $TCID_{50}$/mL
Influenza A Virus, (H1N1)pdm09	$1.4x10^7$ $TCID_{50}$/mL	Parainfluenza Virus serotype 1	$4.45x10^6$ $TCID_{50}$/mL
Influenza A Virus, (H3N2)	$1.1x10^8$ $CEID_{50}$/mL	Parainfluenza Virus serotype 2	$4.45x10^5$ $TCID_{50}$/mL
Influenza B Virus	$1.4x10^7$ $CEID_{50}$/mL	Parainfluenza Virus serotype 3	$8.0x10^7$ $TCID_{50}$/mL
Enterovirus 71	$8.0x10^7$ $TCID_{50}$/mL	Parainfluenza Virus serotype 4	$2.5x10^6$ $TCID_{50}$/mL
Rhinovirus group A	$2.5x10^{6.5}$ $TCID_{50}$/mL	Human Corona virus HKU1 NP protein	0.125mg/mL
Respiratory Syncytial virus type A	$8.0x10^6$ $TCID_{50}$/mL	Human Corona virus HKU1 S protein	250ug/mL
Respiratory Syncytial virus type B	$2.75x10^{5.5}$ $TCID_{50}$/mL		

Strain (Bacteria)	Test Conc.	Strain (Bacteria)	Test Conc.
Legionella pneumophila subsp.	$7.8x10^6$ cfu/mL	*Chlamydophila pneumoniae*	$1.45x10^7$ IFU/mL
Mycoplasma pneumonia	$1.5x10^7$ cfu/mL	Pooled human nasal fluid	1/2 diluent of original sample
Staphylococcus aureus subsp.	$3.2x10^9$ cfu/mL	*Mycobacterium tuberculosis*	2500 IU/mL
Bordetella pertussis	$9.6x10^8$ cfu/mL	*Staphylococcus epidermidis culture*	$8.5x10^7$cfu/mL
Haemophilus influenzae	$1.28x10^8$ dfu/mL	*Candida albicans*	$5.0x10^6$cfu/mL
Streptococcus Pneumoniae	$2.13x10^6$ dfu/mL	*Pneumocystis jirovecii(PJP)*	In-silico

3. Analytical Specificity – Interference test

An interference evaluation showed that the following potentially interfering substances did not affect the test performance of SGTi-flex COVID-19 Ag:

Interfering substance	Test Conc.	Interfering substance	Test Conc.
Albumin	50 mg/mL	Tamiflu (Oseltamivir)	6 mg/mL
Glucose	1.2 mg/mL	Acetaminophen	10 mg/mL
Hemoglobin	4 mg/mL	Ibuprofen	5 mg/mL
Bilirubin	5 mg/mL	Aspirin	2 mg/mL
mucin	1.0 %	Naso GEL	5% v/v
Whole blood	4.0 %	Oxymetazoline	0.1 mg/mL
Phenylephrine hydrochloride	10 mg/mL	Cromolyn	0.03 mg/mL
Dexamethasone	0.6 mg/mL	Zicam	5% v/v
Flunisolide	2.5 mg/mL	Alkalol	10% v/v
Budesonide	1 mg/mL	Mupirocin	10 mg/mL
Benzocaine	5 mg/mL	Fluticasone Sore Throat Phenol	5% v/v
Menthol	40 mg/mL	Sore Throat Phenol Spray	15% v/v
Zanamivir	10 mg/mL	Heparin sodium salt	3000 U/L
Tobramycin	20 mg/mL		

4. High-dose Hook Effect

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

5. Precision test

Repeatability and reproducibility performance results meet 100% of the acceptance criteria.

6. 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.

Nasopharyngeal swabs: The clinical sensitivity (positive percent agreement) was 90.52% and the clinical sensitivity (negative percent agreement) was 100% in a study on direct nasopharyngeal swab samples that were collected within 7 days of symptom onset), which is the period in which the test is intended to be used, and where more than 20% of the samples had a low viral load (Ct>30). The results appear in the Tables below:

SARS-CoV-2 (NP swab)						
DPSO	≤3	≤4	≤5	≤6	**≤7**	>7
PPA(%) (95% CI(%))	99.21 (95.67 ~99.86)	97.39 (93.47 ~98.98)	95.11 (90.97 ~97.41)	93.91 (89.66 ~96.48)	**90.52 (86.06 ~93.65)**	54.84 (37.77 ~70.84)

[Total Clinical Performance for direct nasopharyngeal swabs]

		Reference method (RT-PCR)		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 Ag)	Positive	210	0	210
	Negative	22	336	358
	Total	232	336	568

(1) Sensitivity (Positive percent agreement) : 90.52% (95% CI: 86.06%~93.65%)

(2) Specificity (Negative percent agreement) : 100.00% (95% CI: 98.87%~100.00%)

SARS-CoV-2 (NP swab)			
Ct Value	≤25	≤30	>30
PPA (%) (95% CI(%))	98.74 (95.53~99.65)	98.06 (95.11~99.24)	43.86 (31.77~56.72)

The studies also included direct nasopharyngeal swab samples that were collected more than 7 days after symptom onset, even though the test is not intended to be used on samples collected more than 7 days after symptom onset. When the samples collected more than 7 days after symptom onset were included, the clinical sensitivity was 86.31% and the clinical specificity was 100%. The lower clinical sensitivity is explained by the test being less effective when testing samples that were collected more than 7 days after symptom onset.

[Total Clinical Performance for direct nasopharyngeal swabs (including swabs collected more than 7 days after symptom onset)]

		Reference method (RT-PCR)		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 Ag)	Positive	227	0	227
	Negative	36	493	529
	Total	263	493	756

(1) Sensitivity (Positive percent agreement): 86.31% (95% CI: 81.63%~89.95%)

(2) Specificity (Negative percent agreement): 100.00% (95% CI: 99.23%~100.00%)

Nasal swabs: The clinical sensitivity (positive percent agreement) was 91.37% and the clinical sensitivity (negative percent agreement) was 99.76% in a study on direct nasal swab samples. The study used samples that were collected within 7 days of symptom onset, which is the period in which the test is intended to be used, and where more than 20% of the samples had a low viral load (Ct>30). The results appear in the Tables below:

[Total Clinical Performance for nasal swab]

		Reference method (RT-PCR)		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 Ag)	Positive	286	1	287
	Negative	27	411	438
	Total	313	412	725

(1) Sensitivity (Positive percent agreement): 91.37% (95% CI: 87.74%~94.00%)

(2) Specificity (Negative percent agreement): 99.76% (95% CI: 98.64%~99.96%)

Clinical sensitivity by DPSO and Ct value is as follows.

SARS-CoV-2 (Nasal swab)					
DPSO	≤3	≤4	≤5	≤6	**≤7**
PPA(%) (95% CI(%))	94.07 (88.74 ~96.97)	91.95 (86.95 ~95.15)	92.63 (88.36 ~95.41)	92.42 (88.59 ~95.04)	**91.37 (87.74 ~94.00)**

SARS-CoV-2 (Nasal swab)			
Ct Value	≤25	≤30	>30
PPA (%) (95% CI(%))	100.00 (97.99~100.00)	99.60 (97.74~99.93)	57.58 (45.56~68.76)

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

FURTHER INFORMATION

If you are experiencing problems with the test or for customer support, please contact the **Involution Healthcare Pty Ltd Customer Support Number 1800 960 593 (9am-7pm (AEST) / 9am-8pm (AEDT) 7 days a week).**

You can also contact the TGA to report poor performance or usability issues via the Users Medical Device Incident Report, email (iris@tga.gov.au) or call (1800 809 361).

Information regarding available support services can be obtained by contacting your local State and Territory health departments as below:

Australian Capital Territory Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 www.health.act.gov.au
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (24/7): 137 788 www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline: 1800 020 080 www.health.nt.gov.au
Queensland Department of Health	13HEALTH: 13 432 584 Coronavirus hotline: 134 268 www.health.qld.gov.au
South Australian Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 www.sahealth.sa.gov.au
Tasmanian Department of Health	General enquiries: 1300 135 513 Coronavirus hotline: 1800 671 738 www.health.tas.gov.au
Victorian Department of Health	General enquiries: 1300 650 172 Coronavirus hotline (24/7): 1800 675 398 www.dhhs.vic.gov.au
Western Australia Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline (8am to 6pm Mon-Fri): 1800 595 206 www.healthywa.wa.gov.au

EXPLANATION OF SYMBOLS USED ON PACKAGE

IVD	*In-vitro* diagnostic medical device
Σ 25	Contains sufficient for 25 tests
	Do not reuse.
	Consult instructions for use.
2°C 30°C	Store between 2°C and 30°C
	Caution, consult accompanying documents
LOT	Batch code
	Use by
REF	Reference number
	Manufacturer
CE	The device conforms to EU regulations

MANUFACTURER

SUGENTECH

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