SGTi-flex

IVD REF CAGS900E Cat. No. CAGT001E0, CAGT002E0, CAGT005E0, CAGS025E AUSTRALIA

COVID-19 Ag

INSTRUCTION VIDEO
FOR AUSTRALIA
– SCAN QR CODE

For Self-Testing Use Only
Please read the instructions carefully before you begin testing

PREPARATION BEFORE TEST

1 Wash your hands thoroughly for more than 20 seconds, using soap and warm water, or hand sanitiser.

2 Check the test kit contents. Make sure that nothing is damaged or broken.


Test Cassette


Dropping Cap

Instructions for use

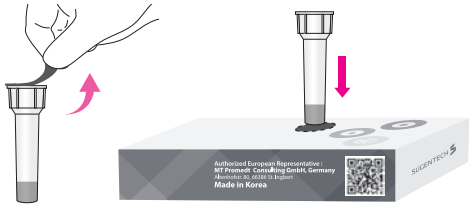

Extraction Buffer


Sample collection Swab

3 All samples and reagents should be stored at room temperature for 15 to 30 minutes prior to testing.

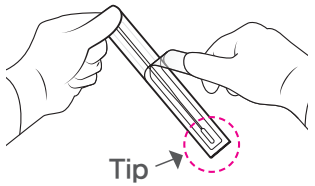
TAKE A SAMPLE WITH A SWAB

4 Remove the sealing foil from the Extraction Buffer Tube. And place the Extraction Buffer Tube in the packing box.

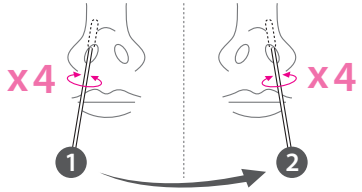


5 Swab is in a sterile wrapper. Open the closed wrapper and take out the swab by holding the handle.

※ **Never touch the fabric tip of the swab with your hands.**

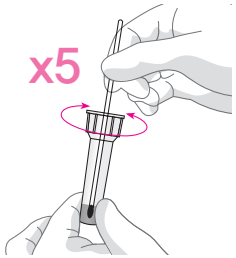


6 Carefully insert the entire absorption tip of the swab (usually 1/2 to 3/4 of an inch (or 1 to 1.5 cm)) inside the nostril and firmly sample the nasal wall at least 4 times. Gently remove swab. Using the same swab, repeat steps in your other nostril.

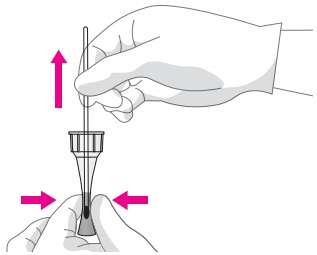


TEST PROCEDURE

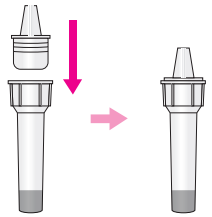
7 Put the the swab into the Extraction Buffer Tube and rotate it more than 5 times to allow extraction.



8 Take the swab out by pressing and squeezing the sides of the tube to extract the remaining liquid from the swab.



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

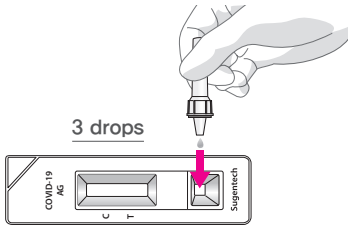


10 Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.

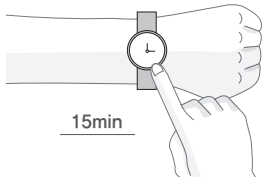
※ **Test Cassette is moisture sensitive so should be used immediately after opening.**

11 Turn the Extraction Buffer Tube integrated Dropping Cap upside down and slowly squeeze **3 drops** onto the sample well of the Test Cassette.

Attention: After each drop is completely absorbed, add the next drop.



12 Please wait 15 minutes after adding the 3 drops to the sample well of the Test Cassette.



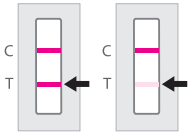
※ **Do not read before 15 min or after 30 min.**

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, you should follow the current guidance on the website of the Commonwealth Department of Health and Aged Care here: https://www.health.gov.au/topics/covid-19/testing-positive. Also see "POSITIVE TEST RESULT" on next page.



※ **Any coloured line in the region of the Test Line (T), whether a strong or a faint colour, should be considered as a positive result.**

2 Negative

If only Control line (C) appears in the result window, it is a negative result for the SARS-CoV-2 antigen.

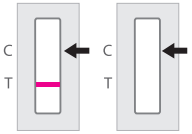
A negative result cannot completely rule out the possibility of a viral infection. Incorrect sampling or low viral load can cause a false negative result. If you feel unwell, seek medical assistance.

3 Invalid

If the Control line (C) fails to appear, the result is invalid.

You should take another test with a new Test Cassette using a freshly collected specimen. Read the operating instructions carefully and repeat the test.

If repeated tests also produce invalid results, please report the details to the sponsor.



SAFETY DISPOSAL

Once you complete the test, put all of the used test items into a bag, then seal that bag and dispose of the sealed bag in your normal household waste.

Wash your hands thoroughly for more than 20 seconds, using soap and warm water, or hand sanitiser, after disposing of used test kit components.

Involution Healthcare Pty Ltd,
Level 36 Gateway, 1 Macquarie Place,
Sydney NSW 2000, Australia
Email: support@involutionhc.com
www.involutionhc.com
Customer Support Number: 1800 960 593 (8:45am to 5:15pm AEST/ AEDT Monday to Friday (excluding public holidays).)

INTENDED PURPOSE – SELF-TEST USE ONLY

The SGTi-flex COVID-19 Ag is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus in nasal swab specimen self-collected from individuals with symptoms, within the first 7 days of symptom onset. The test is used as an aid in the diagnosis of SARS-CoV-2 viral infections. The test is intended to be used in the home or similar environment by a lay person.

PACK SIZES (REF: CAGS900E)

SGTi-flex COVID-19 Ag is available in pack sizes 1, 2, 5 and 25 test. Each pack size includes a Test Cassette, Extraction Buffer, Dropping Cap, Sample Collection Swab and Instructions for Use. The 1, 2 and 5 tests contain 1 IFU, but the 25 test contains 25 IFUs.

PRINCIPLE

SGTi-flex COVID-19 Ag is an immunoassay for qualitative detection of SARS-CoV-2 antigens directly from 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.

STORAGE AND STABILITY

- Store SGTi-flex COVID-19 Ag Test Cassette and Extraction Buffer at 2 to 30°C (36 to 86°F).
- 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.
- The shelf-life of the test kit is 24 months and it is stable until the expiration date marked on the label.

WARNING AND PRECAUTIONS

- For *in-vitro* diagnostic use only.
- For self-testing use only.
- 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.
- 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.
- Extraction buffer contains Triton X-100 at product concentrations classified as low-hazardous. Nevertheless, do not swallow and keep Extraction buffer away from children.
- 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.
- If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.
- If you have a nose piercing, remove the piercing on the side before swabbing.
- If you've had a nosebleed within the last 24 hours, swab only the other nostril or wait 24 hours.
- These kits are only designed for human use.
- Repeat testing within 1 to 3 days is recommended if ongoing suspicion of infection, high risk setting or occupational or other requirement.
- This product can be used for persons aged 2 years or older. An adult should carry out the test on a person aged between 2 and 12 years. Do not use the test on a person under 2 years of age.
- After disposing of the used test items, wash hands thoroughly with soap and water or hand sanitiser.

POSITIVE TEST RESULT

1. If you get a positive result, staying at home protects your community. You should not visit high risk settings such as hospitals, aged care or disability care centres.
2. If you are unwell or need COVID-19 advice for you or someone in your care, talk to your health provider or speak to a nurse by calling the healthdirect helpline on 1800 022 222.
3. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately and tell the operator and paramedics if you tested positive.

LIMITATIONS OF THE SYSTEM

1. The test is for qualitative detection of SARS-CoV-2 antigen in human nasal swab and it does not indicate the quantification of the virus.
2. The test is for in vitro diagnostic use only and self-testing 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-1 (SARS Coronavirus) virus may cause a positive test result. SARS-CoV-1 (SARS Coronavirus) can be detected by the test as a cross reaction.
5. The test can detect the recombinant nucleocapsid protein of the SARS-CoV-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, C_t: 26.68), Delta (B.1.617.2): $5.0x10^2$ $TCID_{50}$/mL ($1.51x10^5$ copies/mL, C_t: 26.13), Omicron (B.1.1.529): $3.75x10^1$ $TCID_{50}$/mL ($2.98x10^5$ copies/mL, C_t: 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 SARS-CoV-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 SGTi-flex COVID-19 Ag when tested using recombinant protein, but cross-reactivity 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 jirovecli (PJP), which is a type of bacteria, has no cross-reactivity 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.

Virus: *Alpha Coronavirus (229E), Beta Coronavirus OC43, Human Coronavirus NL63, Beta Coronavirus (MERS), Beta Coronavirus (SARS-CoV-1), Influenza A/H1N1, Influenza A/H3N2, Influenza B, Enterovirus 71, Rhinovirus group A, RSV type A, RSV Type B, Mumps Virus, Adenovirus type 5, Human Coxsackie B, Human Metapneumovirus, Parainfluenza Virus serotype 1, Parainfluenza Virus serotype 2, Parainfluenza Virus serotype 3, Parainfluenza Virus serotype 4*

Bacteria: *Legionella pneumophila subsp., Mycoplasma pneumonia, Staphylococcus aureus subsp., Bordetella pertussis, Hemophilus influenzae, Streptococcus Pneumoniae, Chlamydophila pneumoniae,* Pooled human nasal fluid, *Mycobacterium tuberculosis, Staphylococcus epidermidis culture, Candida albicans*

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:

Albumin, Glucose, Hemoglobin, Bilirubin, Mucin, Whole Blood, Phenylephrine hydrochloride, Dexamethasone, Flunisolide, Budesonide, Benzocaine, Menthol, Zanamivir, Tobramycin, Tamiflu (Oseltamivir), Acetaminophen, Ibuprofen, Aspirin, Naso GEL, Oxymetazoline, Cromolyn, Zicam, Alkalol, Mupirocin, Fluticasone Propionate, Sore Throat Phenol Spray, Heparin sodium salt

4. Clinical Performance

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted using 408 nasal swab specimens.

The results for nasal swab showed the overall percent was 97.06% (95% CI, 94.96~98.31%). The clinical sensitivity (known as positive agreement) was 90.57% (95% CI, 83.50~94.79%) and the clinical specificity (known as negative agreements) was 99.34% (95% CI, 97.62~99.82%), respectively.

		Reference Method (RT-PCR)		
		Positive	**Negative**	**Total**
SGTi-flex COVID-19 Ag	Positive	96	2	98
	Negative	10	300	310
	Total	106	302	408

The study was performed as a positive sample within 7 days of symptom onset. And more than 20% of the relatively low viral load (Ct>30) positive samples were included.

5. Usability Study

A Usability Study was carried out in the Republic of Korea between 26 July 2021 and 28 October 2021 with lay person users aged between 13 and 79 years(272 adults and 6 teenagers). The results of the self-tests by the lay person users were evaluated by comparative analysis using RT-PCR. The results were a diagnostic sensitivity of 90.24% (74 of 82) and a diagnostic specificity of 100% (196 of 196) when compared with RT-PCR.

Each lay person self-collected nasal swab specimens from their own nasal cavities and self-tested the specimens using SGTi-flex COVID-19 Ag using the Instructions for Use (IFU) and the other items supplied with the test kit. Trained observers watched the lay persons perform all parts of the test process without answering questions or providing instructions. Interpretation of each test result was performed by both the lay person and the trained observer.

The interpretation of the test results was the same for each lay person and the trained observer, except for 2 of the 278 test results. No lay person or trained observer determined that any test result was an invalid test result, even if a lay person had any difficulty with any part of the test process.

The results of the Usability Study showed that 99.6% of lay persons found the IFU very easy or easy to comprehend and that lay persons can perform all the steps in the test process from opening the test kit, self-collect a nasal swab specimen, perform the test, interpret the test result and dispose of the used test items without any problems. The trained observers did not observe any material problems in any part of the test process. As a result, the Usability Study demonstrated that no special training is needed to use the test and that lay persons only need to follow the instructions in the IFU to complete all parts of the test process properly.

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** (8:45am to 5:15pm AEST/AEDT Monday to Friday (excluding public holidays).)

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

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.
2°C 30°C	Store between 2°C and 30°C		Caution
LOT	Batch code		Use by
REF	Reference number		Manufacturer
CE	The device conforms to EU regulations		

MANUFACTURER

SUGENTECH

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