SureScreen Diagnostics

SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab)(Gold) REF COVID19AGVCGAUS2

Before testing, scan the QR code to watch the how to use video.

Video link:
https://surescreen.net.au/covid-19-self-test/

INTENDED USE

The test is used for self-testing. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) (Gold) is a lateral flow chromatographic immunoassay single-use test kit intended for qualitative detection of SARS-CoV-2 that causes COVID-19 with self-collected nasal swab specimen. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19 within the first 7 days of symptom onset as an aid for diagnosis of COVID-19. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

WARNING

- Do not use after the expiration date. Expiration date is printed on the box and test cassette.
- The test cassette should remain in the sealed pouch until ready to use.
- Do not use any nasal sprays 15 minutes prior to testing.
- Children under 12 years of age should be tested by an adult.
- Children under 3 years old should not use this device.
- Users with a nose bleed should not use this device.
- Tests are less reliable in the later phase of infection or asymptomatic individuals
- The extraction buffer contains materials which may create irritation if it comes into contact with the skin or eyes. If the solution contacts with the skin or eye, wash with excess water thoroughly. If irritation persists, please seek medical attention.
- The product has not been made with natural rubber latex however the presence or traces of natural rubber latex in the product as delivered to the end-user cannot be excluded completely
- If you have a nose piercing, remove the piercing before conducting the test.
- These test kits are only designed for human use.

STORAGE AND HANDLING

- Store at room temperature or refrigerated at (2-30˚C). Do not freeze. Do not store in direct sunlight.
- The kit should be used at room temperature (15 C to 30˚C). If the kit has been stored in a cool area (less than 15˚C), leave it at normal room temperature for 20 minutes before using.
- Use a separate test kit for each person.
- You can only use each item in the test kit once. Do not re-use the items. It is for single use only.
- If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.
- Do not touch the swab head when handling the swab.

KIT CONTENT

Kit Content

Component Description	No. in Kits
Test cassette	2
Sterile nasal swabs	2
Extraction buffer vials	2
Sample collection vials	2
Package insert	1

LIMITATIONS

- Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
- Failure to follow these procedures may alter test performance.
- False negative results may occur if a specimen is improperly collected or handled.
- False negative results may occur if inadequate levels of viruses are present in the specimen. Testing should be performed within the first 7 days of symptom onset.
- A negative result does not rule out infection with another type of respiratory virus.
- A negative result means that you are negative or that the viral load is too low to be recognised, if you experience covid type symptoms or are in a high risk setting you should retest in 1 – 3 days and seek medical advice if symptoms persist.
- The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is less reliable in the later phase of infection, it is recommended to use the test within the first 7 days of symptom onset.
- A positive result cannot necessarily determine whether a person is infectious.
- Positive results of COVID-19 can be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors not tested. Refer to Cross Reactivity and Interfering Substances.
- The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a presumptive test only follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary and if unwell seek medical assistance.

PERFORMANCE CHARACTERISTICS

Limit of Detection
The SARS-CoV-2 Antigen Rapid Test estimated to SARS-CoV-2 heat inactivated virus strain at $1000TCID_{50}$/mL.

Sensitivity and Specificity
The SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) has been evaluated with specimens obtained from different clinical sites where the specimens were collected with Nasal Swabs.

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	Result	Positive	Negative	
	Positive	124	4	128
	Negative	5	406	411
Total Results		129	410	539

A 96.1% Sensitivity (124/129 confirmed positives) and a 99.0% Specificity (406/410 confirmed negatives) and 98.3% Accuracy for the study.

LAY USER STUDY

A lay-user study was performed by lay person at 6 different sites in USA to evaluate use of the SARS-CoV-2 Antigen Rapid Test for Home by lay users in a simulated home use environment. In the lay-user self-testing group, the study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. The samples were collected and the tests performed under the observation of professionals, who did not intervene at any stage.

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	Result	Positive	Negative	
	Positive	86	2	88
	Negative	5	326	331
Total Results		91	328	419

A 94.5% Sensitivity (86/91 confirmed positives) and a 99.4% Specificity (326/328 confirmed negatives) and 98.3% Accuracy for the study.

Total 419 lay-users participated in the study, and the results showed that the IFU provided with the test kit was comprehensive for its intended population, the ease of use was suitable for its intended population.

VARIANTS

The SARS-CoV-2 variant Alpha (B.1.1.7), Beta (B.1.351), Gamma(P.1), Delta (B.1.617.2), Omicron (B.1.1.529) and new variant (B.1.640.2) could be detected out by the device at specific concentrations.

CROSS-REACTIVITY

The SARS-CoV-2 Antigen Rapid Test Cassette has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenza, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens. The results showed no cross reactivity. The test kit cannot differentiate between SARS-CoV-1 and SARS-CoV-2.

INTERFERING SUBSTANCES

No substances showed any interference with the COVID-19 Antigen Rapid Test (Swab): Ambroxol Hydrochloride Tablets (7.5mg/mL), Beclomethasone Dipropionate Nasal Aerosol, Dextromethorphan Hydrobromide Oral Solution (1.5mg/ml), Triamcinolone Acetonide Nasal Spray, Mucosolvan Ambroxol Hydrochloride Oral Solution, Azelastine Hydrochloride Nasal Spray, Nasal cleansing solution NaCl (5g/L), Fluticasone Propionate Nasal Spray, Listerine mouthwash, Physiological Seawater Nasal Spray, Scope mouthwash, Tobramycin Eye Drops, Haemoglobin (10g/L), Whole blood (4%), Bilirubin (8000mg/dl), Mucin (0.05%), Nasal antibioitic (Mupirocin Ointment), 0.5% BSA-PBS, Oxymetazoline Hydrochloride Spray.

FREQUENTLY ASKED QUESTIONS

1. When should the test be used?
SARS-CoV-2 antigen can be detected in acute respiratory tract infection, it is recommended to run the test in symptomatic individuals with acute onset of fever, cough; or 3 or more of the following signs or symptoms: Fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status. Testing is also recommended if individuals are contacts of confirmed COVID-19 cases or probable cases and to at-risk health workers.

2. Can the result be incorrect?
The results are considered accurate if the instructions are carefully respected. Nevertheless, the result can be incorrect if inadequate sampling volume or the SARS-CoV-2 Antigen Rapid Test is compromised or contaminated or if the number of extraction buffer drops are less than 3 or more than 4. Due to immunological principles involved, there exist the chance of false results and warnings and limitations of the test are outlined on this information sheet.
3. How to interpret the test if the color and the intensity of the lines are different?
The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the color intensity of the test line is.

For CUSTOMER SUPPORT HELPLINE: Call (02) 90610577 9am-7pm (AEST), 7 days per week.
For information on the correct use of this test and for interpretation of the test results.

LOCAL CONTACT DETAILS

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT STATE AND TERRITORY CONTACT NUMBERS.

Follow the guidance from your local state or territory health department for guidance on confirmation testing if necessary and if unwell seek medical assistance.

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)
02 6207 7244 or https://health.act.gov.au/

New South Wales Coronavirus Helpline (Service NSW 24/7)
137 788 or https://www.health.nsw.gov.au/

Northern Territory Coronavirus National Hotline (National Helpline)
1800 020 080 or https://health.nt.gov.au/

Queensland Coronavirus Helpline (134COVID)
134 268 or https://www.health.qld.gov.au/

South Australia Coronavirus Helpline (9am -5 pm Daily)
1800 253 787 or https://www.sahealth.sa.gov.au/

Tasmanian Public Health Hotline (Coronavirus)
1800 671 738 or https://www.health.tas.gov.au/

Victoria Coronavirus Hotline (24/7)
1800 675 398 or https://www.coronavirus.vic.gov.au

Western Australia Coronavirus Hotline 13COVID (8am- 6pm Mon-Fri)
1800 595 206 or https://www.healthywa.wa.gov.au/

Contact the TGA to report poor performance or usability issues in the self-test environment
(report an issue via the Users Medical Device Incident Report, email: iris@tga.gov.au or call 1800 809 361)

INDEX OF SYMBOLS

2°C 30°C	Store at 2 - 30°C	STERILE EO	Sterilized using ethylene oxide		Manufacturer	EC REP	European Authorized Representative
LOT	Lot number		Expiry date		Do not re-use		Don't use the product when the package is damaged
	Consult instructions for use	Σ 2	Contains sufficient for 2 tests	IVD	In vitro diagnostic medical device		Consult 'Advice about taking the test' section for general guidance and warnings
REF	Catalogue number		Keep away from sunlight		Keep dry		

Manufacturer:
SureScreen Diagnostics Ltd. 1 Prime Parkway, Prime Enterprise Park, Derby, DE1 3QB, UK.

EC REP SureScreen Ireland Ltd.
9 Exchange Place I.F.S.C Dublin 1, Ireland

Swab Information:
Zhejiang Gongdong Medical Technology Co., Ltd. No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, People's Republic of China

Jiangsu ChangFeng Medical Industry Co., LTD. Touqiao Town, Guangling District, Yangzhou, 225109 Jiangsu P.R. China

Australian Sponsor:
SureScreen Australia Pty limited.
4, 181-187 Taren Point Road, Caringbah
2229 New South Wales, Australia
www.surescreen.net.au

SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab)(Gold) Instruction Guide

Before testing, scan the QR code to watch the how to use video.
Video link:
https://surescreen.net.au/covid-19-self-test/

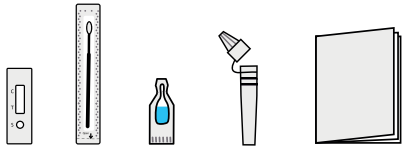
BEFORE TESTING

- The kit should be used at room temperature (15°C to 30°C). If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 20 minutes before using.
- Check the expiration date on the box. Do not use if the kit if it has been damaged or has expired
- Do not use any nasal sprays 15 minutes prior to testing.

PREPARE YOUR TEST AREA

1. Read this instruction guide carefully. **This test may be different from those you have used before.**
2. Clear, clean and dry a flat surface immediately before starting the test.
3. Clean your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser.

CHECK YOUR KIT CONTENTS



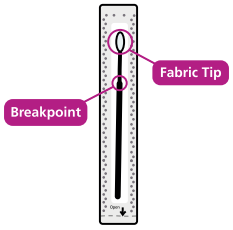
You will need each of these items to complete the test: Test cassette, Sterile nasal swab, Extraction buffer vial, Sample collection vial, Package insert.

Note: A timer (clock, timer, phone etc.) is also required, but not provided.

SET UP YOUR TEST

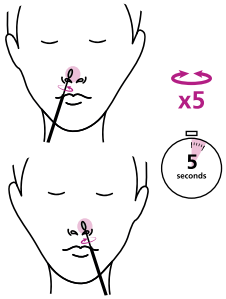
1. Take the test cassette out of the sealed pouch and place it onto a clean flat surface. **WARNING: Once opened, use within 1 hour, or the test will be void.**

2. Place the extraction tube in the extraction tube holder (perforated circular area on lid of the box) to avoid spilling the liquid.
3. Carefully twist to snap open the liquid vial. Open it away from your face and be careful not to spill any of the liquid.
4. Open the extraction tube and gently squeeze all of the liquid from the vial into the tube. Take care and discard the empty liquid vial.
5. Gently blow your nose into a tissue and throw the tissue away in a closed bin.
6. Clean your hands thoroughly again for 20 seconds using soap and warm water or use sanitiser.
7. Pick up the swab and identify the fabric tip.
8. Peel open the wrap from the end opposite the fabric tip. **Do not touch the tip and you should discard if this has happened.**



TAKE YOUR SWAB SAMPLE

Only insert the fabric tip on the swab 1.5cm inside each nostril.



9. Gently wipe the swab around the inside of your nostril in a circular motion **5 times for at least 5 seconds.** Slowly remove it. Immediately sample the second nostril at Step 10.

10. Using the same swab, place the fabric tip just inside about 1.5cm inside your nose. Gently wipe the swab around the inside of your nostril in a circular motion **5 times for at least 5 seconds.**

DOING A TEST ON SOMEONE ELSE

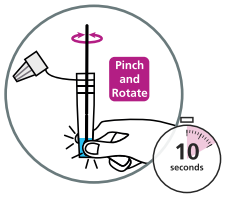
If testing another person the same process should be used when setting up the test and sampling. Hands should be washed by both persons each time.

Follow steps 9 and 10 to take the sample, inserting the fabric tip on the swab 1.5cm inside each nostril. No force is required.

Children under 12 should be tested by an adult.

PROCESS THE SWAB SAMPLE

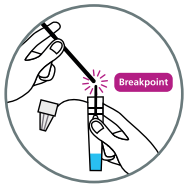
For best performance, test the swab as soon as possible after collecting your sample.



11. Pick up the extraction tube and place the swab's fabric tip in the extraction tube, so it is in the liquid.

    Press the swab head firmly against the inside of the tube body by pinching the bottom of the tube with your thumb and fingers.

    Whilst pinching, rotate the swab for at least 10 seconds.

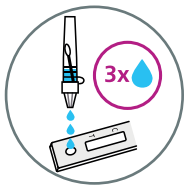


12. Slightly lift the nasal swab then break the swab on the "breakpoint" position. Leave the swab head in the extraction tube.

    Place the swab handle in the plastic waste bag provided.

13. Fit the dropper cap tightly onto the top of the extraction tube.

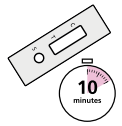
14. **Avoid touching the test kit and results window area where the sample is added.** Ensure the test cassette is on a clean and flat surface.



15. Gently squeeze the extraction tube to place **3 drops** of the liquid into the sample well (S) on the test strip.

    Make sure that you are dropping liquid and not an air bubble.

    Discard the extraction tube in to the waste bag.

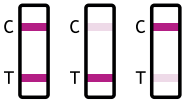


16. Start a timer and wait 10 minutes before reading the result. Do not move the test once it is running. Interpret the result after 10 minutes. Do not read after 20 minutes.

    You must wait the full 10 minutes' development time before you read your test result.

POSITIVE RESULT

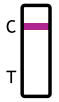
Two lines appear. One coloured line should be in the control line region (C), and another coloured line should be in the test line region (T) **Two lines, one next to C and one next to T, even faint lines, shows the test is positive.**



If you get a positive result, it is likely you are currently infected with COVID-19 and risk infecting others. You should self-isolate. Follow the guidance from your local State or Territory health department for guidance on confirmatory testing if necessary and isolation requirements for you and close contacts.

NEGATIVE RESULT

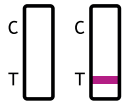
One coloured line appears in the control line region (C). No line appears in the test line region (T).



If you get a negative result, you were likely not infectious at the time you took the test. A negative test result, however, **is not a guarantee that you do not have COVID-19.** If the test result is negative or non-reactive and clinical symptoms persist or being in a high risk setting or where there is an occupational risk, it is recommended to test again with a new test 1-3 days later or contact the nearest Covid test centre using the rules of your local authority.

VOID RESULT

Control line (C) fails to appear.



If you get a void result, this means that the test has not run correctly and it is not possible to say if you had the virus when the test was done. You need to use another test from the pack as soon as possible. **Do not reuse anything from the first test, and start the test procedure from step 1.**

If the problem persists, discontinue using the test kit immediately and contact the Australian Sponsor: Call (02) 90610577 9am-7pm (AEST).

DISPOSAL INFORMATION

Safely dispose of your test
Once your test is complete, put all of the used contents in the waste bag provided and put this in your general household waste.

Wash your hands thoroughly after disposal.

For CUSTOMER SUPPORT HELPLINE: Call (02) 90610577 9am-7pm (AEST), 7 days per week. For information on the correct use of this test and for interpretation of the test results.

Effective Date: 29 November 2021.