SureScreen Diagnostics

SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab)(Gold) Package Insert

A rapid test for the qualitative detection of COVID-19 Antigen in a Nasal Swab.
For use only by individuals who have been given appropriate training for in vitro diagnostic use.

【INTENDED USE】

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 Antigen in a Nasal Swab. 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 diarrhoea are found in a few cases.

【PRINCIPLE】

The SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal swabs. In this test, antibodies specific to the N protein of SARS-CoV-2 are separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibodies to N protein of SARS-CoV-2 that are coated onto gold colloid particles. The mixture migrates up the membrane to react with the antibodies to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test region. The presence of this colored line in the test region indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein antibody gold colloid particles conjugate and anti-SARS-CoV-2 Nucleocapsid protein antibody coated onto the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For use only by individuals given appropriate training for in vitro diagnostic use. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. Used tests should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. If the solution contacts with the skin or eye, wash with excess water thoroughly. If irritation persists, please seek medical attention.
7. Wear gloves if possible. Alternatively, sterilize hands with alcohol gel before and after handling the samples, avoid touching the reagent membrane and sample well.
8. Tests are less reliable in the later phase of infection or asymptomatic individuals.
9. Children under 3 years old should not be tested.

【STORAGE AND STABILITY】

Store as packaged at room temperature, or refrigerated (2-30℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials provided

25 x Test cassettes	25 x Extraction Buffer Tube	25 x Sterile Nasal Swabs
1 x Package Insert	1 x Workstation	

Materials required but not provided

Timer and Gloves/PPE

【SPECIMEN COLLECTION AND PREPARATION】

- Nasal Swab

Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, the patient should be instructed to **blow their nose**. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ⅗ to 1 of an inch (1.5 to 2.5cm))inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Take approximately 15 seconds to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with the same swab before testing.

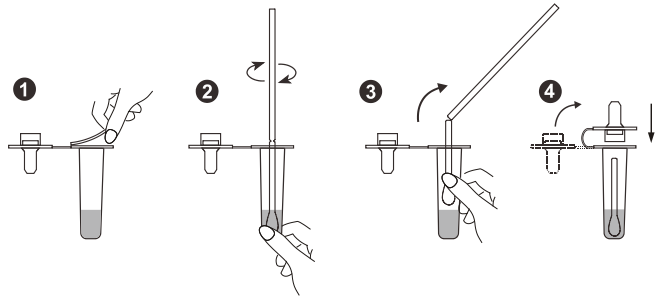
Specimen Collection Instruction

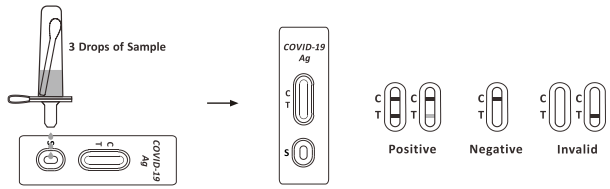
For Nasal Swab

【DIRECTIONS FOR USE】

Specimen collection, buffer extraction and test development should be done following directions with minimal delay. Allow the test, specimen, and extraction buffer tube to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Tear off the aluminum foil on the extraction buffer tube. See illustration 1.
3. Place the swab specimen in the extraction buffer tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction buffer tube body to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the extraction buffer tube as you remove it to expel as much liquid as possible from the swab. Slightly lift the nasal swab then break the swab on the “break point” position. Leave the swab head in the sample collection vial and dispose of swab handle in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction buffer tube. Place the test cassette on a clean and flat surface. See illustration 4.
6. Hold the dropper vertically and transfer 3 drops of the sample solution (approx.80μL) to the sample well and then start the timer
7. Read the result at 10 minutes. Do not interpret the result after 20 minutes
8. Once completed the test, safely dispose the test contents into the medical waste bin. Wash your hands thoroughly after disposal





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that SARS-CoV-2 Antigen is not present in the specimen, or is present below the detectable level of the test.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

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 adequate membrane wicking. Control solutions are not provided in this kit. It is however recommended where possible, for positive and negative controls to be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. **Contact the Australian sponsor for further details regarding the external control test availability, SureScreen Australia Pty Ltd. 02 9061 0577**

【LIMITATIONS】

1. The SARS-CoV-2 Antigen Rapid Test Cassette is for use only by individuals who have been given appropriate training for in vitro diagnostic use. Neither the quantitative value in the SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
3. Failure to follow these procedures may alter test performance.
4. False negative results may occur if a specimen is improperly collected or handled.
5. 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.
6. A negative result does not rule out infection with another type of respiratory virus.
7. 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.
8. 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.
9. A positive result cannot necessarily determine whether a person is infectious to SARS-CoV-2.
10. Positive results of SARS-CoV-2 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.

【PERFORMANCE CHARACTERISTICS】

Limit of Detection

The SARS-CoV-2 Antigen Rapid Test estimated to SARS-CoV-2 heat inactivated virus strain at 1000$TCID_{50}$/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)	Results	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.

Data stratification by Ct Values:

Rapid Antigen test	CT < 25	CT ≥ 25<30	CT ≥ 30
Positive	68	30	26
Negative	0	2	2
Total	68	32	28
PPA	100%	93.75%	92.86%
95% CI	94.05%-100%	79.19%-99.23%	76.50%-99.12%
Sample %	52.71%	24.8%	21.7%

Data Stratification by date of symptom onset:

Days Since symptom	PCR Positive	Rapid Antigen Positive	PPA	95% CI
0	6	6	100.00%	54.07%-100.00%
1	13	12	92.31%	66.13%-99.82%
2	27	26	96.30%	81.65%-99.91%
3	27	26	96.30%	81.65%-99.91%
4	11	11	100.00%	71.51%-100.00%
5	10	10	100.00%	69.15%-100.00%
6	4	4	100.00%	39.76%-100.00%
7	7	7	100.00%	59.04%-100.00%

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 by the device at specific concentrations.

Hook Effect
There is no dose hook effect when the concentration of SARS-CoV-2 antigen is lower than 1.63mg/ml, and the concentration of positive substance is lower than $1.0x10^5TCID_{50}$/mL.

Precision
The SARS-CoV-2 Antigen Rapid Test Cassette was tested within-lot, between-lot, within-day, between-day, within-site, between-site, and between-user using negative, strong positive, and weak positive specimen with 20 replicates between-lot. The specimens were correctly identified >99% of the time.

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, MERScoronavirus positive specimens. The results showed no cross reactivity. The test kit cannot differentiate between SARS-CoV-1 and SARS-CoV-2.

Interfering Substances
Following substances showed no interference with the SARS-CoV-2 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.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.

【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 5	Contains sufficient for 5 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 0123

Jiangsu ChangFeng Medical Industry Co., LTD. Touqiao Town, Guangling District, Yangzhou, 225109 Jiangsu P.R. China 0197

Australian Sponsor:
SureScreen Australia Pty limited.
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