SureScreen Diagnostics

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

A rapid test for the qualitative detection of SARS-CoV-2 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 Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigen in a Nasal swab. The identification is based on monoclonal antibodies specific to the Nucleocapsid （N）protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infection.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of other people getting infected; asymptomatic and symptomatic infected people can both be an infectious source. Based on the current epidemiological investigations, the incubation period is 1 to 14 days, mostly 3 to 7 days. 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 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 coloured line in the test region. The presence of this coloured line in the test region indicates a positive result. To serve as a procedural control, a coloured 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. Wear gloves if possible. Alternatively, sterilize hands with alcohol gel before and after handling the samples, avoid touching the reagent membrane and sample well.

【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 Exaction Buffer Vials	25 x Sample Collection Vials
25 x Sterile Nasal Swabs	1 x Package Insert	1 x Workstation
25 x Sealing Caps		

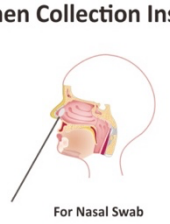
Materials required but not provided

Timer and Gloves/PPE

【SPECIMEN COLLECTION AND PREPARATION】

- Nasal Swab

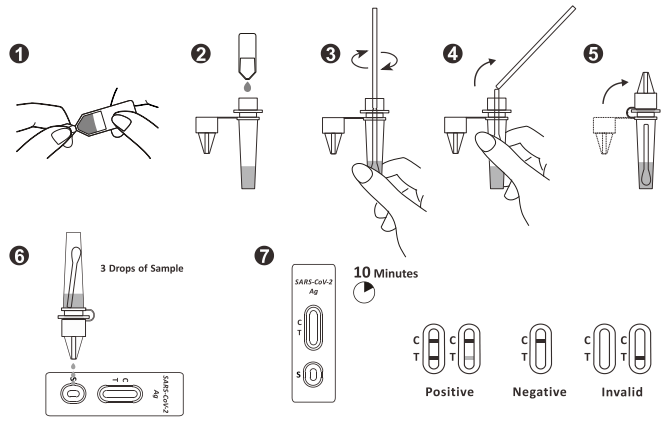
Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, the patient should be instructed to **blow their nose**. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ⅗ to 1 of an inch (1.5 to 2.5cm))inside the nostril and firmly sample the nasal 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**.

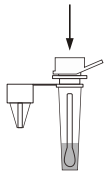


【DIRECTIONS FOR USE】

Allow the test, specimen, and extraction buffer 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. Place the sample collection vial in the workstation. Twist the handle of the extraction buffer vial and add **ALL** extraction buffer (approx. 300µl) to the sample collection vial. See illustration 1&2.
3. Place the swab specimen in the sample collection vial. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the sample collection vial body to release the antigen in the swab. See illustration 3.
4. Slightly lift the nasal swab then beak 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 4(a).
5. Fit the dropper tip on top of the sample collection vial. Place the test cassette on a clean and flat surface. See illustration 5.
6. Hold the dropper vertically and transfer 3 drops of the sample solution (approx.80µL) to the sample well and then start the timer. Read the result at 10 minutes. See illustration 6 and 7. **Do not interpret the result after 20 minutes.**
7. If the sample is required for further laboratory analysis, remove the dropper tip and fix the sealing cap to the vial for transportation.





Close the sealed cap for PCR test if necessary

Specimen Transport and Storage

Specimens should be tested as soon as possible after collection. Based on data from in-house studies, specimens collected from nasal swabs are stable for up to 96 hours at 2° to 8°C for RT-PCR analysis. Results obtained with specimens collected past this time can give erroneous results in PCR testing for COVID-19.

【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured 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 colour 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 colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured 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 coloured 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.

【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 nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
3. The SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR, and/or should be interpreted and followed up in line with national/regional guidance. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the swab is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
7. A positive result for SARS-CoV-2 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
8. 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.
9. Positive results may be due to current infection with acute non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43 or 229E.
10. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. The extraction reagent has the ability to kill the virus, but it cannot inactivate 100% of the virus. The method of inactivating the virus should be referred to as

recommended by WHO/CDC, or according to local regulations.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

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. The Nasal Swabs were randomised and blind tested by operators following the instructions for use. RT-PCR was used as the reference method for the SARS-CoV-2 Antigen Rapid Test Cassette. Specimens were considered positive if PCR indicated a positive result.

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	124	4	128
	Negative	5	406	411
Total Results		129	410	539

Relative Sensitivity: 96.1% (95%CI*:91.2%-98.7%)*
Relative Specificity: 99.0% (95%CI*:97.5%-99.7%)*
Relative accuracy: 98.3% (95%CI*:96.9%-99.2%)*
* Confidence Intervals

Detection Limit

The LOD for the SARS-CoV-2 Antigen Rapid Test Cassette (Nasal Swab) was established using limiting dilutions of an inactivated viral sample. The control (ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15 x 10^7TCID$_{50}$/mL. The Estimated LOD is 1000 TCID$_{50}$/mL.

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 parainfluenzae, 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.

【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

	Consult instructions for use		Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Manufacturer

SureScreen Diagnostics Ltd
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Number: SSDCOVID19AGVCG260221
Effective date: 2021-02-26