SG Diagnostics
Committed to Quality of Health

SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)

The SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based) has received Provisional Authorisation from the Health Sciences Authority in Singapore

For *In Vitro* Diagnostic Use Only
For Use with Nasal, Nasopharyngeal or Oropharyngeal Swab Sample
Catalogue number SG0010

INTENDED USE

The SG Diagnostics COVID-19 Antigen Rapid Test Kit is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is intended for use with nasal, nasopharyngeal or oropharyngeal swab samples in individuals who are suspected of COVID-19. This test utilizes a lateral flow immunoassay technology for the qualitative detection of spike and nucleocapsid protein antigens of SARS-CoV-2 in individuals with known or suspected COVID-19.

Results are for the identification of SARS-CoV-2 spike and nucleocapsid protein antigens. Antigens are generally detectable in swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with individual's clinical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results from individuals with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for disease management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or disease management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The SG Diagnostics COVID-19 Antigen Rapid Test Kit is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests.

SUMMARY AND EXPLANATION OF THE TEST

The novel coronavirus SARS-COV-2 is the causative pathogen for the global pandemic of COVID-19 that has spread worldwide. Most infected people will experience mild to severe respiratory illness and recover without special treatment. The most common symptoms are fever, cough and fatigue. Older people and those with underlying medical problems (e.g. cardiovascular disease, diabetes, chronic respiratory disease and cancer) are more likely to develop serious illness and serious symptoms include difficulty breathing or shortness of breath, chest pain and loss of speech or movement. It typically takes 5 – 6 days for someone that is infected with the virus for symptoms to appear but it can take up to 14 days in some individuals.

The SG Diagnostics COVID-19 Antigen Rapid Test Kit is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from swabs. The SG Diagnostics COVID-19 Antigen Rapid Test Kit contains all the components required to carry out an assay for SARS-CoV-2.

PRINCIPLES OF THE PROCEDURE

The SG Diagnostics COVID-19 Antigen Rapid Test Kit is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 spike and nucleocapsid protein antigens from swab samples via the double antibody sandwich method. After loading, the sample will diffuse upwards from the charging end by capillary action, and then the SARS-CoV-2 spike and nucleocapsid protein antigens in the sample will combine with the antibody in the marker pad to form colloidal gold antibody-antigen complex; the complex continues to diffuse upwards to the nitrocellulose membrane with the sample, and is then blocked by Test (T) Line packed with antibody to form colloidal gold labeled antibody-antigen-immune complex. The unblocked colloidal gold complex continues to move upwards and combines with the Control (C) line (quality control line), indicating that the reaction is completed.

To perform the test, a nasal, nasopharyngeal or oropharyngeal swab sample is collected from the patient with kit-provided swab and the swab sample is extracted by the sample eluent. 4 drops of the extracted sample are applied to the sample well of the Test Cassette. Test results are interpreted visually at 10 minutes based on the presence or absence of visually detectable red colored lines. Results should not be read after 30 minutes.

REAGENTS AND MATERIALS

Materials Provided

Test Cassettes: A test cassette consists of test strip, packed individually in sealed desiccant foil pouch. The test strip consists of absorbent paper, nitrocellulose membrane, sample pad, colloidal gold marker pad and polyvinyl chloride pane. Nitrocellulose membrane T Line is packed with about 1 mg/mL SARS-CoV-2 monoclonal antibody, while C Line is packed with about 1 mg/mL internal reference protein C, and the marker pad contains about 40 OD anti-mouse SARS-CoV-2 antibody colloidal gold complex.
Disposable Swabs: Single-use sterile swabs for sample collection
Sample Eluent: 0.5mL of phosphate buffer (0.01M, pH7.4±0.2) with surfactant
Product Insert
Materials Required but not Provided: Clock, timer or stopwatch

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This test is intended only for the testing of nasal and oropharyngeal (throat) swabs for the detection of SARS-CoV-2 protein antigens, not for any other viruses or pathogens.
3. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
4. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
5. Proper sample collection and handling are essential for correct results.
6. Do not store specimens in viral transport media for specimen storage.
7. Swabs in the kit are approved for use with SG Diagnostics COVID-19 Antigen Rapid Test Kit. Do not use other swabs.
8. Do not touch swab tip when handling swab sample.
9. Leave test cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not use any kit components with visible damage.
11. Do not mix components from different kit lots.
12. Do not use kit past its expiration date.
13. All kit components are single use items. Do not use with multiple samples.
14. All components of this kit should be discarded as Biohazard waste according to legislated regulatory requirements.

STORAGE AND STABILITY

Store kit at 4-30°C. The SG Diagnostics COVID-19 Antigen Rapid Test Kit is stable until the expiration date marked on the outer packaging and containers. Once the foil pouch is opened (4°C-30°C, humidity <65%), the test cassette must be used within 1 hour.

QUALITY CONTROL

SG Diagnostics COVID-19 Antigen Rapid Test Kit has built-in procedural controls. The control line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection

- **Nasal Swab Specimen (Recommended)**

It is important to obtain as much secretion as possible. Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

- **Oropharyngeal Swab Specimen (Optional)**

It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when removing the swab.

- **Nasopharyngeal Swab Specimen (Optional)**

It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.

Specimen Handling

Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

SPECIMEN TRANSPORT AND STORAGE

Note: Do not return the swab to the original paper packaging after specimen collection.

For best performance, sample should be eluted from the swab within 1 hour after collection and be tested as soon as possible afterwards. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15 – 30°C) for up to 1 hour prior to testing. If there is a delay in testing of more than 1 hour, please store samples at refrigeration temperature (2 – 8°C) for up to 1 day or at -70°C and below for long-term storage. Ensure the swab fits securely within the tube and the cap is tightly closed. Chilled samples should be rewarmed to room temperature before testing. Frozen samples should be thawed and rewarmed to room temperature before testing. Repeated freezing and thawing of sample should be avoided.

TEST PROCEDURE

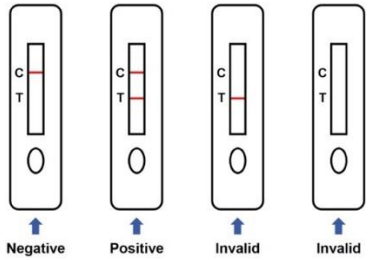
Note: For best performance, sample should be eluted from the swab within 1 hour after collection and be tested as soon as possible afterwards.

Note: The test cassette must be at room temperature before use, and the test must be operated at room temperature.

1. Remove the white cap from the elution tube and insert the patient swab into it.
2. Roll the swab at least 10 times while pressing the swab tip against the bottom and side of the elution tube.
3. Squeeze or press the swab against the side of the tube to remove as much liquid as possible, then dispose of the swab in biohazard waste.
4. Cover the elution tube tightly with the nozzle connected to the tube.
5. Open the test cassette package and lay it flat.
6. Add 4 drops of the test sample into the oval sample well (marked), the sample will be drawn by capillary action into the test strip.
7. Start and timer and wait for the coloured band to appear. Read the results after 10 minutes. The result is invalid after 30 minutes.
8. Dispose of the used Swab, Sample Eluent Vial and Test Cassette in the appropriate biohazard waste.

RESULT INTERPRETATION

Note: In a valid device, a red line appears at the Control Line position, confirming that the sample has flowed through the test strip and the reagents are working.



The test results are analyzed as follows:

Negative
A negative specimen will give a single red colored Control (C) Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

Positive
A positive specimen will give two red colored lines (T Line and C Line). This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible red colored Sample Line is positive.

Invalid
If no lines are seen, if just the red Test Line is seen, or if the red Control Line is not seen, the assay is invalid. Invalid tests should be repeated.

LIMITATIONS
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the SG Diagnostics COVID-19 Antigen Rapid Test Kit was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Specimens should be tested as quickly as possible after specimen collection.
- False-negative results may occur if a specimen is improperly collected or handled. False negative results may occur if swabs are stored in their original packaging after specimen collection.
- False results may occur if specimens are tested past 1 hour of collection. False-negative results may occur if inadequate extraction is done.
- False-negative results may occur if less than 4 drops of the extracted sample are applied to the charging hole of the Test Cassette.
- False-negative results could potentially arise from mutations occurring in the antibody target regions in the SARS-CoV-2 antigen.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

PRODUCT PERFORMANCE INDICATORS

Clinical Performance
The clinical performance of SG Diagnostics COVID-19 Antigen Rapid Test Kit was validated using clinical samples from both symptomatic and asymptomatic patients. The clinical samples were secretions extracted from human nasal, nasopharyngeal or oropharyngeal swab and analysis by RT-PCR showed that 362 were clinically positive and 683 were clinically negative. The test kit results are shown in the table below.

Method		RT-PCR		Total
		Positive	Negative	
SG Diagnostics COVID-19 Antigen Rapid Test Kit	Positive	352	7	359
	Negative	10	676	686
Total		362	683	1045

SG Diagnostics COVID-19 Antigen Rapid Test Kit could detect COVID-19 antigen in nasal swab specimens with high clinical performance sensitivity and specificity listed below:
- Sensitivity: 97.24% (95%CI: 94.98% to 98.67%)
- Specificity: 98.98% (95%CI: 97.90% to 99.59%)
- Total agreement: 98.37% (95%CI: 97.41% to 99.05%)

Analytical Sensitivity: Limit of Detection (LoD)
The confirmed LoD was 50 $TCID_{50}$/mL.

Analytical Specificity: Cross Reactivity (Exclusivity) and Microbial Interference
SG Diagnostics COVID-19 Antigen Rapid Test Kit showed no cross-reactivity with the following potentially cross-reactive common organisms - Human coronavirus (229E, HKU1, OC43 and NL63), Middle East respiratory syndrome (MERS) coronavirus, Adenovirus, Enterovirus, Influenza A (H1N1 and H3N2) and B viruses, Avian influenza virus, Parainfluenza type 1-4, Measles virus, Human metapneumovirus, Mumps virus, Rhinovirus, Epstein-Barr virus, Respiratory syncytial virus, Staphylococcus aureus, Streptococcus pneumoniae, Staphylococcus epidermidis, Mycobacterium tuberculosis, Legionella pneumophila, Haemophilus influenza, Streptococcus pyogenes, Chlamydia pneumoniae, Mycoplasma pneumoniae, Candida albicans, organisms that make up normal respiratory flora, and organism(s) that causes parapertussis and pneumocystis.

SG Diagnostics COVID-19 Antigen Rapid Test Kit showed no microbial interference when testing was done with samples containing 100 $TCID_{50}$/mL of SARS-CoV-2 and potentially cross-reactive common organisms.

Interfering Substances Effect
The test performance was not affected by any of the interfering substances listed below at the concentrations tested.

- Alpha-interferon (3,000,000 U)
- Budesonide (0.64 nmol/L)
- Oxymetazoline (500 µg/mL)
- Meropenem (1 µg/mL)
- Beclomethasone (200 µg/L)
- Peramivir (20 µg/mL)
- Ceftriaxone (100 mg/mL)
- Sodium chloride (0.9%)
- Mucin (10 mg/mL)
- Ribavirin (2.0 mg/mL)
- Oseltamivir (375 µg/mL)
- Azithromycin (0.15 g/L)
- Tobramycin (0.125 mg/mL)
- Levofloxacin (5 µg/mL)
- Viscous liquid
- Whole blood

High-dose Hook Effect
SARS-CoV-2 positive sample of 1.92×10^5 $TCID_{50}$/mL was tested and no hook effect was observed.

SYMBOLS

EC REP	Authorized Representative in the European Community		Consult instructions for use
IVD	*In vitro* diagnostic medical device	STERILE	Sterile
	Stored at 4 – 30 °C		Single use only
CE	CE mark		Expiration date
REF	Catalog number	LOT	Lot number
	Date of manufacture		Manufacturer site

MANUFACTURER CONTACT INFORMATION

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