

For in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 Antigen Rapid Test Cassette (Saliva) is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in saliva from individuals who are suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in saliva during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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 do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.

The COVID-19 Antigen Rapid Test Cassette (Saliva) is intended for use by medical professionals or trained operators who are proficient in performing lateral flow tests. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

[SUMMARY]

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, 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 COVID-19 Antigen Rapid Test Cassette (Saliva) is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated with color microparticles is used as detector and sprayed on conjugation pad. During the test, SARS-CoV-2 antigen in the specimen interacts with SARS-CoV-2 antibody conjugated with color microparticles making antigen-antibody labeled complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody. A colored test line (T) would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. Absence of the T line suggests a negative result. The control line (C) is used for procedural control, and should always appear if the test procedure is performed properly.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and individuals trained in point of care settings.
- Do not use this product as the sole basis to diagnose or exclude

SARS-CoV-2 infection or to inform infection status of COVID-19.

- Do not use this product after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

Materials Provided

- 20 Test Cassettes: each cassette with desiccant in individual foil pouch
- 20 Extraction Reagents: ampoule containing 0.3 mL of extraction reagent
- 20 Saliva Collectors
- 20 Collection tubes
- 20 Droppers
- 1 Work Station
- 1 Package Insert

Materials Required but not Provided

- Timer

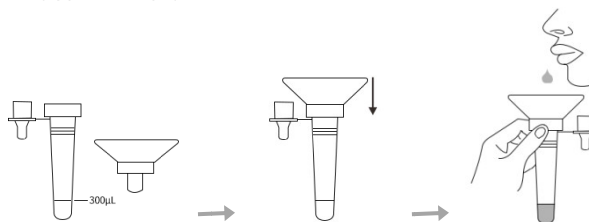
[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30°C or 40-86°F). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN COLLECTION AND PREPARATION]

DO NOT place anything in the mouth including food, drink, gum or tobacco products for at least 30 minutes prior to collection.

Use the collection tube and saliva collector to collect saliva. Insert the saliva collector into the collection tube, then put the saliva collector close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be at the scale mark (approx. 300µL). If the volume of saliva is too much, use a dropper to remove the excess saliva until the final solution at the scale mark (approx. 300µL).



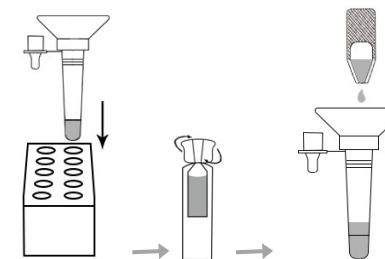
Specimen Transport and Storage

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection.

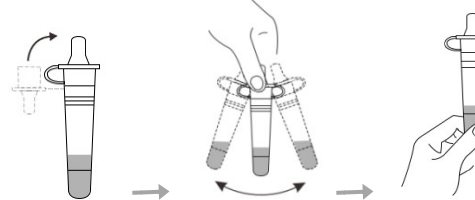
[TEST PROCEDURE]

Note: Allow the test cassettes, reagents and specimens to equilibrate to room temperature (15-30°C or 59-86°F) prior to testing.

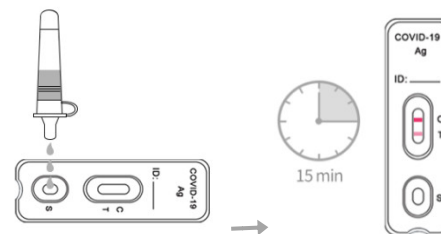
- Place the collection tube with saliva collector which has saliva in the work station. Unscrew the lid of an extraction reagent. Add all of the extraction reagents into the collection tube.



- Discard the saliva collector; Cover the collection tube with the dropper tip onto the collection tube. Shake the collection tube more than three times vigorously to mix the saliva and the extraction reagent, then squeeze the mixed solution ten times to allow the saliva to be thoroughly mixed.



- Remove the test cassette from the sealed pouch.
- Reverse the collection tube, holding the tube upright, transfer 3 drops (approximately 100µL) slowly to the specimen well (S) of the test cassette, then start the timer.
- Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.



[INTERPRETATION OF RESULTS]

Positive		Two lines appear. One colored line appears at the control region (C), and another colored line appears at the test region (T), regardless of the intensity of the test line.
Negative		One colored line appears at the control region (C), and no line appears at the test region (T).
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 using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The product is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antigen of the specimens.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- A physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- A negative result can occur if the quantity of SARS-CoV-2 antigens present in the specimen is below the detection threshold of the assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test.

[PERFORMANCE CHARACTERISTICS]

Clinical Performance

The clinical performance of COVID-19 Antigen Rapid Test Cassette (Saliva) was established in prospective studies with specimens collected from 645 individual symptomatic patients (within 7 days of onset) and asymptomatic patients who were suspected of COVID-19.

Summary data of COVID-19 Antigen Rapid Test as below:

The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The sensitivity was calculated for the different Ct value range (Ct value ≤ 30 and Ct value ≤ 37).

COVID-19 Antigen		RT-PCR (Ct value ≤ 30)		Total
		Positive	Negative	
CLUNGENE®	Positive	120	2	122
	Negative	4	483	487
Total		124	485	609

PPA (Ct ≤ 30): 96.8% (120/124), (95%CI: 92.0% ~ 98.7%)

NPA: 99.6% (483/485), (95%CI: 98.5% ~ 99.9%)

COVID-19 Antigen		RT-PCR (Ct value ≤ 37)		Total
		Positive	Negative	
CLUNGENE®	Positive	146	2	148
	Negative	14	483	497
Total		160	485	645

PPA (Ct ≤ 37): 91.3% (146/160), (95%CI: 85.9% ~ 94.7%)

NPA: 99.6% (483/485), (95%CI: 98.5% ~ 99.9%)

PPA - Positive Percent Agreement (Sensitivity)

NPA - Negative Percent Agreement (Specificity)

Limit of Detection (Analytical Sensitivity)

The study used cultured SARS-CoV-2 virus (Isolate Hong Kong/VM20001061/2020, NR-52282), which is heat inactivated and spiked into saliva. The Limit of Detection (LoD) is 8.6×10^2 TCID₅₀/mL.

Cross Reactivity (Analytical Specificity)

Cross reactivity was evaluated by testing 32 commensal and pathogenic

microorganisms that may be present in the oral cavity.

No cross-reactivity was observed with recombinant MERS-CoV NP protein when tested at the concentration of 50 µg/mL.

No cross-reactivity was observed with the following viruses when tested at the concentration of 1.0×10^6 PFU/mL: Influenza A (H1N1), Influenza A (H1N1pdm09), Influenza A (H3N2), Influenza B (Yamagata), Influenza B (Victoria), Adenovirus (type 1, 2, 3, 5, 7, 55), Human metapneumovirus, Parainfluenza virus (type 1, 2, 3, 4), Respiratory syncytial virus, Enterovirus, Rhinovirus, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1.

No cross-reactivity was observed with the following bacteria when tested at the concentration of 1.0×10^7 CFU/mL: Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumoniae, Candida albicans, Staphylococcus aureus.

Interference

The following potential interference substances were evaluated with the COVID-19 Antigen Rapid Test Cassette (Saliva) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
Mucin	2%	Whole blood	4%
Benzocaine	5 mg/mL	Menthol	10 mg/mL
Saline nasal spray	15%	Phenylephrine	15%
Oxymetazoline	15%	Histamine dihydrochloride	10 mg/mL
Tobramycin	5 µg/mL	Mupirocin	10 mg/mL
Oseltamivir phosphate	10 mg/mL	Zanamivir	5 mg/mL
Arbidol	5 mg/mL	Ribavirin	5 mg/mL
Fluticasone propionate	5%	Dexamethasone	5 mg/mL
Triamcinolone	10 mg/mL		

High-dose Hook Effect

The COVID-19 Antigen Rapid Test Cassette (Saliva) was tested up to 1.15×10^5 TCID₅₀/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.



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Index of Symbol



Do not reuse



For in vitro diagnostic use only



Store between 4-30°C



Consult instructions for use



Lot number



Contains sufficient for <n> tests



Use by



Keep away from sunlight



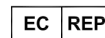
Keep dry



Do not use if package is damaged



Manufacturer



Authorized representative in the European Community

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Effective Date: January 11, 2021