COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab) Package Insert

A rapid test for the qualitative detection of COVID-19 antigen in Saliva and Nasopharyngeal Swab.

For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 Antigen Rapid Test Cassette(Saliva/Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Saliva and Nasopharyngeal Swab. The identification is based on the monoclonal antibodies specific for the Nucleocapsid（N）protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of COVID-19 infections.

【SUMMARY】

The novel coronaviruses 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/Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in saliva and Nasopharyngeal Swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions 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 particles and anti-SARS-CoV-2 Nucleocapsid protein coated on the membrane.

【PRECAUTIONS】

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

1. For professional in vitro diagnostic use only. 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 infection agent.
4. The used test should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves when 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.

【SPECIMEN COLLECTION AND PREPARATION】

The COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab)can be performed using Saliva and Nasopharyngeal Swab specimens. The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

● **To collect Saliva Specimen:**

♦ Use the collection tube to collect saliva, install saliva collector, and collect Saliva specimen as follows:

Important: Before collecting saliva relax your cheeks and gently massage cheeks with fingers for 15-30 seconds, Place the tongue against the upper and lower jaws and roots to enrich the saliva.

Put the collection tube with saliva collector close to lips, gently spit saliva into.

Gently tap the bottom of the tube on a surface or shake the collection tube with saliva collector, until the saliva flows into the collection tube.The volume of saliva needs to be between two scale marks(approx. 150-300μl)on the collection tube.Discard the saliva collector once sufficient saliva sample is collected.

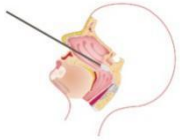
If the volume of saliva is too much, use a dropper or pipette to remove the excess saliva until the final solution is between the two scale marks(approx. 150-300μl).

♦ For best performance, direct Saliva specimens should be tested as soon as possible after collection. If immediate testing is not possible:

- the Saliva specimen can be stored at room temperature in an airtight container for not more than 2 hours.
- The extracted Saliva sample in the extraction tube can be stored at room temperature for 2 hours or at 2-8°C for 2 hours.

●**To collect Nasopharyngeal swab Specimen:**

♦Insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.



Do not return the nasopharyngeal swab to the original paper packaging.

♦For best performance, direct nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible:

- the nasopharyngeal swab can be stored at room temperature in an airtight container for not more than 24 hours.
- The extracted sample in the extraction tube can be stored at room temperature for 24 hours or at 2-8°C for 2 days.

【MATERIALS】

Materials provided

• Test cassettes • Extraction Reagents • Collection Tubes • Saliva collectors
• Sterile Swabs • Droppers • Package Insert • Workstation

Materials required but not provided

• Timer • Pipette

【DIRECTIONS FOR USE】

Allow the test, specimen, 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 assay is performed immediately after opening the foil pouch.
2. Extract the COVID-19 antigen according to the specimen type.

● **For Saliva Specimen:**

♦ Place the collection tube which contains the saliva in the workstation. Twist the top off the extraction reagent bottle taking care not to squeeze the middle area containing liquid. Hold the extraction reagent bottle upside down vertically and squeeze the bottle to let the solution drop into the extraction tube freely without touching the edge of the tube. Add all of the extraction buffer (Approx. 300 μL) to the collection tube.

♦ Lid the cap onto the specimen collection tube.Shake the specimen collection tube more than three times vigorously to mix the saliva and the extraction buffer, then squeeze the mixed solution ten times to allow the saliva to be thoroughly mixed.

● **For Nasopharyngeal swab Specimen:**

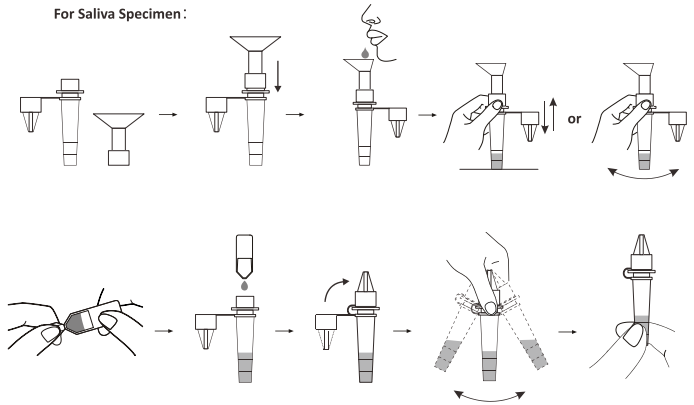
♦ Place the collection tube in the workstation. Open the cap of the collection tube.Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add all of the extraction buffer (Approx. 300 μL) to the collection tube.

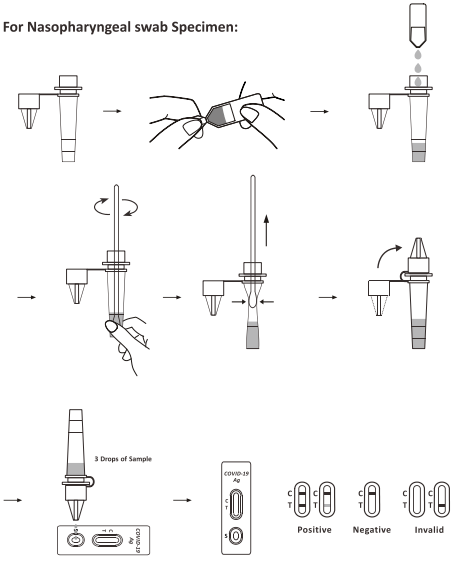
♦ Place the swab specimen in the collection tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

♦ Remove the swab while squeezing the swab head against the inside of the collection tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

♦ Lid the cap onto the specimen collection tube.

3. Place the test cassette on a clean and level surface. Invert the specimen collection tube and transfer 3 full drops of the extracted specimen(approximately 80μL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S).
4. Read the result at 10 minutes. Do not interpret the result after 20 minutes.





【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 COVID-19 was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 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 COVID-19 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 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】

1. The COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab) is for professional in vitro diagnostic use only. The test should be used for the detection of COVID-19 Antigen in Saliva and Nasopharyngeal Swab.. 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 saliva and Nasopharyngeal Swab sample. False negatives may result from improper sample collection or storage.
3. The COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal 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. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the saliva is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the saliva specimen may interfere with test performance and may yield a false positive result.
7. A positive result for COVID-19 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. Extraction reagent has the ability to kill the virus, but it cannot inactivate 100% of the virus. The method of inactivating the virus can be referred to: what method is recommended by WHO/CDC, or it can be handled according to local regulations.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab) Specimens were considered positive if PCR indicated a positive result.

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	241	0	241
	Negative	19	324	343
Total Results		260	324	584

Relative Sensitivity: 92.7% (95%CI*:88.8%-95.5%)

Relative Specificity: ＞99.9%(95%CI*: 99.1%-100.0%)

Relative accuracy: 96.7% (95%CI*:95.0%-98.0%)*

* Confidence Intervals

Detection Limit

The LOD for the COVID-19 Antigen Rapid Test Cassette(Saliva/Nasopharyngeal Swab) was established using limiting dilutions of a viral sample inactivated. The material(ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15 x 10^7TCID50/mL. The Estimated LOD is 1000 TCID50/mL.

Cross Reactivity

The COVID-19 Antigen Rapid Test Cassette (Saliva/Nasopharyngeal Swab) 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】

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3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

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