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

COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasopharynx.
For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens.

Results are for the detection of SARS-CoV-2 Antigens. An antigen is generally detectable in upper respiratory specimens 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 preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. 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.

The COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel.

【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. 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 (Nasopharyngeal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimen. SARS-CoV-2 antibody is coated in test line region. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains anti-SARS-COV-2 antibody as the capture reagent, anti-SARS-COV-2 antibody as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

【PRECAUTIONS】

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
9. The used test should be discarded according to local regulations.
10. Humidity and temperature can adversely affect results.

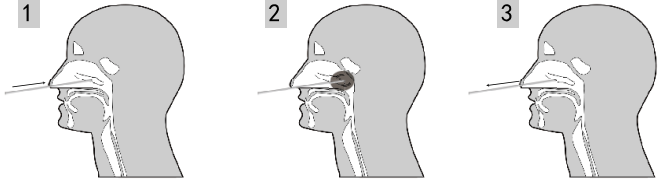
【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). 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】

Specimen Collection

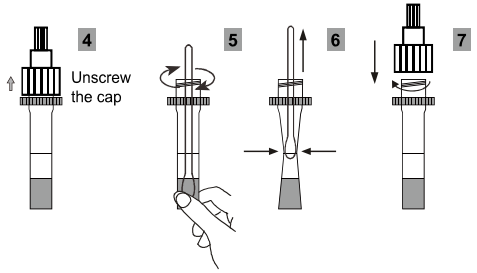
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



***NOTE**: Swabs samples should be tested as soon as possible after collection. If swabs are not been processed immediately, it should be placed into a dry, sterile, and tightly sealed plastic tube for storage, based on data generated from influenza virus, the swab specimen was stable for up to 8 hours at room temperature and 24 hours at 2-8°C.

Specimen Preparation

4. Unscrew the cap of the specimen collection tube.
5. Insert the swab specimen into the specimen collection tube. Press against the inner wall of the tube and stir the swab for approximately 10 seconds while pressing the swab head against the inner wall of the tube to release the antigens in the collection tube.
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
7. Tighten the cap onto the specimen collection tube.



***NOTE**: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

【MATERIALS】

Materials provided

• Test cassettes • Sterile Swabs • Package Insert
• Specimen Collection Tubes with Extraction Buffer

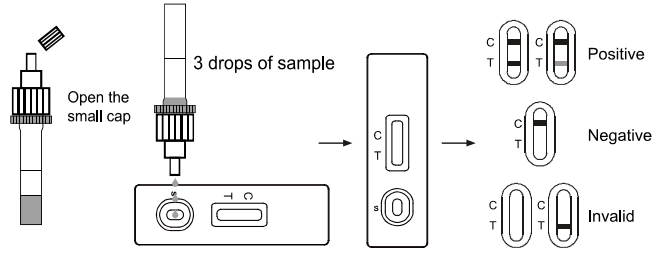
Materials required but not provided

• Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) 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. Invert the specimen collection tube and add **3 drops of the extracted specimen** (approx.75µl) to the specimen well(S) and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of COVID-19 antigens in the sample.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of COVID-19 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line 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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.[1]

【LIMITATIONS】

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 Antigen Rapid Test (Nasopharyngeal swab) is for *in vitro* diagnostic use only. This test should be used for detection of SARS-CoV-2 Antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
3. The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a

molecular diagnostic device to rule out infection in these individuals.

6. The test will show negative results under the following conditions: The titer of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
7. 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.
8. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
10. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

【EXPECTED VALUES】

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 95%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test (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 (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Nasopharyngeal Swab Specimen

COVID-19 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen	Positive	17	1	18
	Negative	3	59	62
Total		20	60	80
Relative Sensitivity		85.0% (95%CI*: 62.1%~96.8%)		
Relative Specificity		98.3% (95%CI*: 91.1%~>99.9%)		
Accuracy		95.0% (95%CI*: 87.7%~98.6%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The COVID-19 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at the concentrations listed:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated. **LD50** = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision

Intra-Assay＆Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) have been tested using negative, SARS-COV-2 Antigen weak and SARS-COV-2 Antigen Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10^8 org/ml and all found to be negative when tested with the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab):

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Nesseria subllava	*Streptococcus sp group F*

【BIBLIOGRAPHY】

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501