



SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-11815 English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens.

For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples 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, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. 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.

The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

SUMMARY

The novel coronaviruses belong to the β genus.¹ 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 SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens.

When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15 minutes based on the presence or absence of visually colored lines. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies coated particles on the membrane. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

MATERIALS

Materials Provided

- Test Cassettes
- Positive Control Swab
- Disposable Swabs*
- Extraction Buffer Tubes
- Negative Control Swab
- Package Insert

* The Disposable Swabs are produced by another manufacturer.

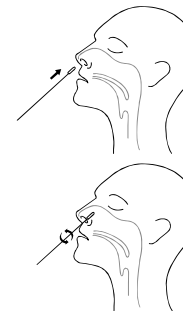
Materials Required But Not Provided

- Personal Protective Equipment
- Timer

SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- To collect a nasal swab sample:

1. Carefully insert a Disposable Swab, **provided with your kit**, into one nostril. Using gentle rotation, push the swab up to 2.5 cm (1 inch) from the edge of the nostril.
2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.



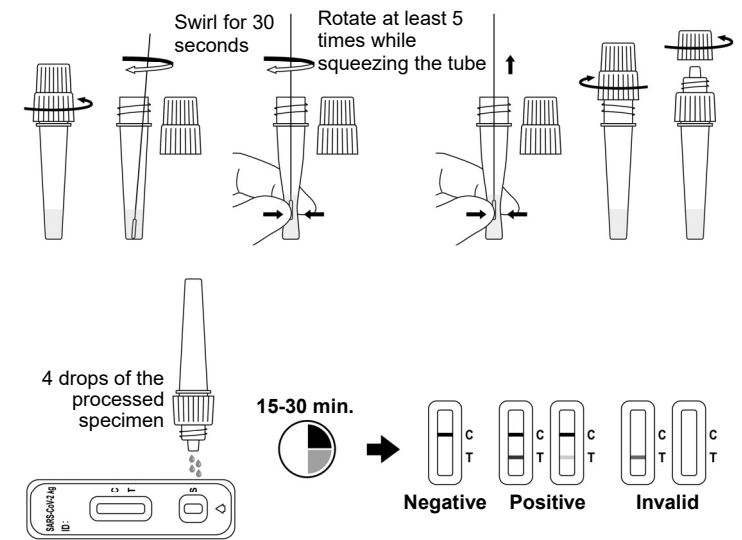
3. Using the same swab, repeat this process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.



DIRECTIONS FOR USE

Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Unscrew the dropper cap from the extraction buffer tube without squeezing.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Screw the dropper cap firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
 - a. Unscrew the small cap from the dropper tip.
 - b. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
 - c. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15-30 minutes. **Do not read the result after 30 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Only one colored control line appears in the control region (C). No apparent colored line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected.

POSITIVE:* Two distinct colored lines appear. One line in the control line region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected.

***NOTE:** The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the **"DIRECTIONS FOR USE"** section to perform the control test.

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.
5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
(If the differentiation of specific SARS viruses and strains is needed, additional testing is required.)

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method	RT-PCR		Total Results
	Negative	Positive	
SARS-CoV-2 Antigen Rapid Test	Negative	1	270
	Positive	33	34
Total Results	270	34	304

Relative Sensitivity: 97.1% (83.8%-99.9%)*

Relative Specificity: 99.6% (97.7%-99.9%)*

Accuracy: 99.3% (97.5%-99.9%)*

*95% Confidence Intervals

Limit of Detection (LoD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The viral sample was spiked with negative human nasal sample pool into a serial of concentrations. Each level was tested for 30 replicates. The results show that the LOD is 1.6×10^2 TCID₅₀/mL.

Sample SARS-CoV-2 Concentration	% Positive (Tests)
1.28×10^3 TCID ₅₀ /mL	100% (30/30)
6.4×10^2 TCID ₅₀ /mL	100% (30/30)
3.2×10^2 TCID ₅₀ /mL	100% (30/30)
1.6×10^2 TCID ₅₀ /mL	96.7% (29/30)
8×10^1 TCID ₅₀ /mL	0% (0/30)

Cross-Reactivity and Interference

No cross reactivity was observed with specimens from patients infected with coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU1^{1,2}, parainfluenza virus type (Type 1, Type 2, Type 3 and Type 4), Influenza A/B, Human rhinovirus, Human Bocavirus, Human respiratory syncytial virus, Human metapneumovirus, Human adenovirus, Enterovirus, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, MERS-coronavirus, Pneumocystis jirovecii. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

The interfering substances (Whole Blood, Dafenlin Oxymetazoline Hydrochloride Spray, Mometasone Furoate Nasal Spray, Fluticasone Propionate, Physiological Seawater Nasal Cleaner) with a certain concentration have no interference on the test of SARS-CoV-2 Antigen Rapid Test.

PRECISION

Intra-Assay

Within-run precision was determined using 10 replicates of specimens: negative control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.












Inter-Assay

Between-run precision was determined using 10 independent assays on the same specimen: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer		Contains sufficient for <n> tests		Temperature limit
	<i>In vitro</i> diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use		Batch code		Catalogue number
	Authorized representative in the European Community		Date of manufacture		

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