COVID-19 Antigen Rapid Test

English

REF ICOV5002-B001

For in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab, nasal swab or oropharyngeal swab 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 nasopharyngeal swab, nasal swab and oropharyngeal swab 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 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 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

- 1Test Cassette: each cassette with desiccant in individual foil pouch
- 1 Extraction Reagent Tube: tube sealed with foil film containing 0.3 mL of extraction reagent
- 1 Sterilized Swab: single use swab for specimen collection
- 1 Package Insert

Materials Required but not Provided

- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30 ℃ or 40-86 ℉). 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]

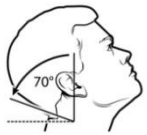
Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to obtain accurate test results.

Acceptable specimen type for testing is a direct swab specimen or a swab in viral transport media (VTM) without denaturing agents. Use freshly collected direct swab specimens for best test performance.

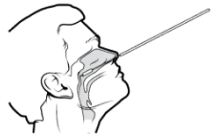
Prepare the extraction reagent tube according to the Test Procedure and use the sterile swab provided in the kit for specimen collection.

Nasopharyngeal Swab Specimen Collection

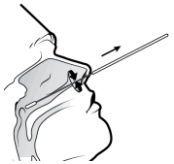
1. Remove the swab from the package.



2. Tilt patient's head back about 70°.



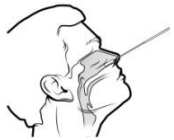
3. Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Gently rub and roll the swab, 3-5 times. Leave swab in place for several seconds to absorb secretions.



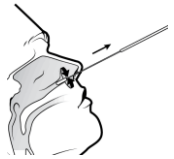
4. Slowly remove swab while rotating it.

Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the tip of swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

Nasal Swab Specimen Collection



1. While gently rotating the swab, insert swab about 2.5 cm (1 inch) into nostril until resistance is met at turbinates.



2. Rotate the swab 5 times against nasal wall and **repeat in other nostril using the same swab**.

Oropharyngeal Swab Specimen Collection

Insert swab into the posterior pharynx and tonsillar areas. Rub the swab 5 times against both tonsillar pillars and posterior pharyngeal wall and avoid touching the tongue, teeth, and gums.

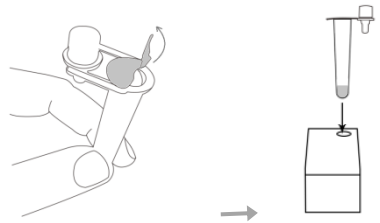
Specimen Transport and Storage

Do not return the swab to the original swab packaging. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8 ℃ for no more than 24 hours; Store at -70 ℃ for a long time, but avoid repeated freeze-thaw cycles.

[TEST PROCEDURE]

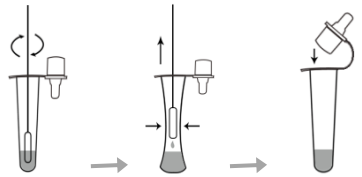
Note: Allow the test cassettes, reagents and specimens to equilibrate to room temperature (15-30 ℃ or 59-86 ℉) prior to testing.

- Carefully tear off the sealed foil film on the extraction reagent tube. Do not let the extraction reagent flow out.
- Press the hole on the box and insert the extraction reagent tube into the hole.
- Sampling refers to section 'Specimen Collection'.



Direct Swab Test Procedure

1. Insert the swab specimen into the extraction reagent tube which contains extraction reagent. Roll the swab at least 5 times while pressing the head against the bottom and side of the extraction reagent tube. **Leave the swab in the extraction reagent tube for one minute.**
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. The extracted solution will be used as test sample.
3. Cover the extraction reagent tube with the connected dropper tip tightly.



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

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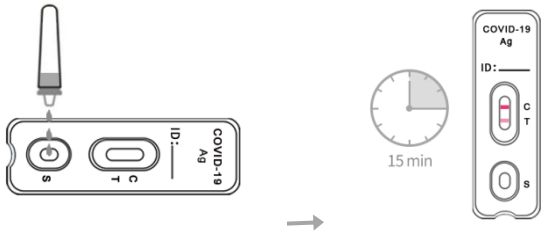
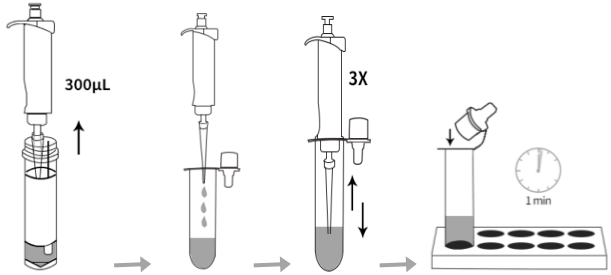


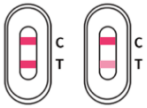
Swab in Viral Transport Media (VTM) Test Procedure

1. Insert the swab specimen into the transport tube containing a maximum of 3 mL VTM without denaturing agents.
2. Mix the specimen stored in VTM by vortexing.
3. Transfer 300 µL of the VTM solution containing specimen into the extraction reagent tube which contains extraction reagent with a calibrated micropipette. Homogeneous mixture by pipetting up and down.
4. Cover the extraction reagent tube with the connected dropper tip tightly, **and let the extracted solution stand for one minute**.



5. Follow Steps 4 – 6 of the **Direct Swab Test Procedure** above.

[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), irregardless 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

For nasopharyngeal swab:

The clinical performance of COVID-19 Antigen Rapid Test was evaluated by prospective clinical studies conducted in Greece, in which nasopharyngeal swabs were collected from sequentially recruited participants and tested. Participants included symptomatic individuals within the first seven days after symptom onset, or individuals with other epidemiological reasons to suspect COVID-19 infection, or asymptomatic individuals without known exposure. The test showed a sensitivity of 96.0% (266/277, 95% CI: 93.0%-97.8%) and a specificity of 100% (925/925, 95% CI: 99.6%-100%) compared to the RT-PCR results from nasopharyngeal swabs.

A genotyping analysis on unselected 88 PCR-positive specimens identified 31 cases of Omicron infection, those comparator PCR Ct values ranged from 10.5 to 31.1 (7/31 at Ct >25) and all of which were positive by COVID-19 Antigen Rapid Test. Thus, the test performance is not affected by Omicron variant.

For nasal swab:

The clinical performance of COVID-19 Antigen Rapid Test was evaluated by prospective clinical studies conducted in Poland, in which nasal swabs were collected from sequentially recruited participants and tested. Participants included symptomatic individuals within the first seven days after symptom onset, or individuals with other epidemiological reasons to suspect COVID-19 infection. The test showed a sensitivity of 95.5% (105/110, 95% CI: 89.8%-98.0%) and a specificity of 100% (450/450, 95% CI: 99.2%-100%) compared to the RT-PCR results from nasopharyngeal swabs.

Summary of COVID-19 Antigen Rapid Test performances compared with the RT-PCR

Country	**Greece**	**Poland**
Subjects (n)	1202	560
Sample type, antigen test	Nasopharyngeal swab	Nasal swab
PCR positive (n, %)	277, 23.0%	110, 19.6%
PCR negative (n, %)	925, 77.0%	450, 80.4%
Sensitivity (%) [95% CI]	96.0% [93.0%, 97.8%]	95.5% [89.8%, 98.0%]
Sensitivity Ct ≤25 (%) [95% CI]	100% [98.2%, 100%]	97.5% [91.2%, 99.3%]
Sensitivity Ct ≤30 (%) [95% CI]	99.6% [97.7%, 99.9%]	97.1% [91.7%, 99.0%]
Specificity (%) [95% CI]	100% [99.6%, 100%]	100% [99.2%, 100%]

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 nasopharyngeal swab specimen. The Limit of Detection (LoD) is 5.7 $\times 10^2$ $TCID_{50}$/mL.

Cross-Reactivity (Analytical Specificity)

Cross-reactivity was evaluated by testing 32 commensal and pathogenic microorganisms that may be present in the nasal cavity.

No cross-reactivity was observed with MERS-Coronavirus when tested at the concentration of 1.8 $\times 10^5$ $TCID_{50}$/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 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%	Mupirocin	10 mg/mL
Tobramycin	5 µg/mL	Zanamivir	5 mg/mL
Oseltamivir phosphate	10 mg/mL	Ribavirin	5 mg/mL
Arbidol	5 mg/mL	Dexamethasone	5 mg/mL
Fluticasone propionate	5%	Histamine dihydrochloride	10 mg/mL
Triamcinolone	10 mg/mL		

High-dose Hook Effect

The COVID-19 Antigen Rapid Test was tested up to 1.2×10^6 $TCID_{50}$/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.

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Index of Symbol

- Do not reuse
- Store between 4-30 ℃
- Lot number
- Use by
- Keep dry
- Manufacturer
- Catalogue number
- *In vitro* diagnostic medical device
- Consult instructions for use
- Contains sufficient for <n> tests
- Keep away from sunlight
- Do not use if package is damaged
- Authorized representative in the European Community

Version No.: 2.0
Effective Date: March 31, 2022

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