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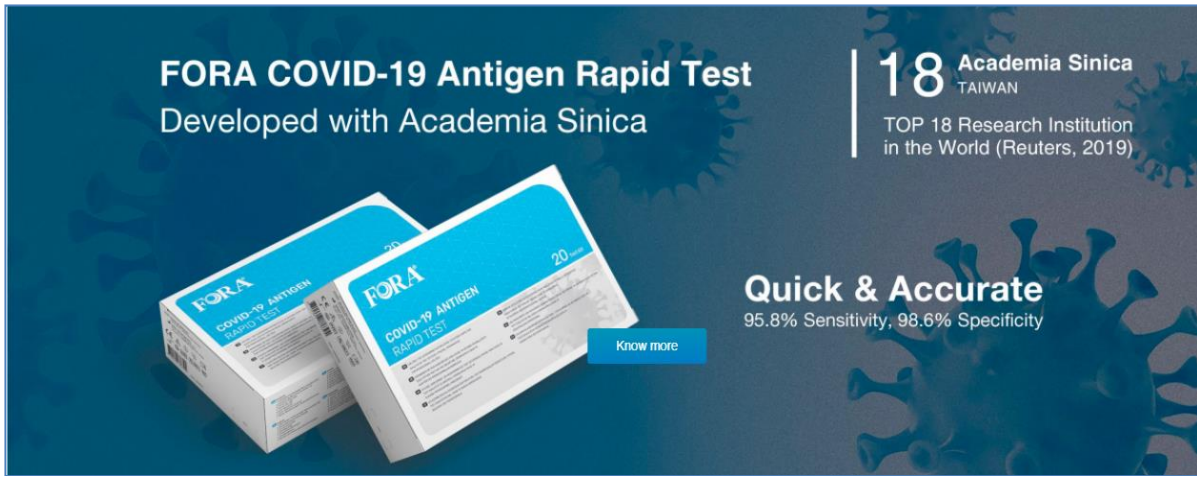
FORA COVID-19 Antigen Rapid Test FAQs



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Q1. What is COVID-19?

The coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is a coronavirus identified as the cause of an outbreak of respiratory illnesses first detected in Wuhan, China. The WHO declared COVID-19 a pandemic on March 11, 2020. COVID-19 has caused millions of confirmed cases worldwide, including hundreds and thousands of deaths, and the statistics are still increasing. It has been reported that symptoms ranging from mild to severe may appear in 2-14 days after exposure to SARS-CoV-2. People with COVID-19 may suffer from these symptoms: fever, cough, and shortness of breath.

Q2. What are the symptoms of SARS-CoV-2 infection? Are they serious?

The main clinical manifestations of confirmed cases of COVID-19 are fever, general fatigue, respiratory symptoms, and dry cough, while some may even develop respiratory failure. Symptoms can progress to severe pneumonia, acute respiratory distress, multiple organ failure, and shock in severe cases. According to available epidemiological data reported so far, despite some deaths, most patients eventually recover. Most mortality cases have underlying diseases, such as diabetes mellitus, chronic liver disease, renal insufficiency, and cardiovascular disease, etc.

Q3. When should I seek medical care for COVID-19?

If you think you have been exposed to COVID-19, it is important to monitor for symptoms closely. Seek medical attention immediately if you develop severe symptoms, especially if you experience:

- Severe trouble breathing (such as being unable to talk without gasping for air)
- Continuous pain or pressure in your chest
- Feeling confused or having difficulty waking up

- Blue-colored lips or face
- Any other emergency signs or symptoms

If you seek medical attention, be sure to do the following to help keep the facility and others from possibly getting infected or exposed.

1. Call ahead before visiting the facility.
2. Tell any healthcare provider that you may have COVID-19.
3. Avoid using public transportation, ridesharing, or taxis.
4. Put on a facemask before you enter any healthcare facility.

Q4. Who are the target users for this FORA COVID-19 Antigen Rapid Test?

Individuals who are suspected of COVID-19 by their healthcare provider are the target users. The FORA COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in in-vitro diagnostic procedures and individuals trained in point of care settings.

Q5. What is the test principle of FORA COVID-19 Antigen Rapid Test?

FORA COVID-19 Antigen Rapid Test is a lateral flow chromatographic immunoassay in a sandwich design with colloidal gold as an indicator. The FORA COVID-19 Antigen Rapid Test detects antigen from the SARS-CoV-2 in fresh nasal and nasopharyngeal samples directly from patients suspected of COVID-19 by their healthcare provider. This test allows the detection of SARS-CoV and SARS-CoV-2. The test detects but does not differentiate between the two viruses.

Q6. How accurate is FORA COVID-19 Antigen Rapid Test?

According to the literature of Target Product Profile Point of Care SARS-CoV-2 detection tests, the acceptance criteria of clinical sensitivity (or Positive Percent Agreement) should be greater than 80%. And the clinical specificity (or Negative Percent Agreement) should be greater than 95%.

FORA COVID-19 Antigen Rapid Test has shown sensitivity and specificity of 95.8% and 98.6% in clinical tests, which meets the acceptance criteria (sensitivity≥ 80% and specificity≥ 95%).

Q7. What are the advantages of FORA COVID-19 Antigen Rapid Test?

Antigen tests detect proteins of the SARS-CoV-2 virus that form during the infection cycle and indicate that a person has an active infection. Rapid antigen tests offer several significant benefits. They are highly portable, scalable, easy-to-use, and provide a flexible approach to help more people access reliable and cost-effective testing. FORA COVID-19 Antigen Rapid Test uses the monoclonal antibody that specifically binds to the nucleocapsid (N) protein to determine the presence of the SARS-CoV-2 antigen and provides a fast result in only 15 minutes.

In collaboration with Taiwan's Academia Sinica, the top 1 research institution in Taiwan and the top 18 innovative research institutions globally, FORA COVID-19 Antigen Rapid Test was developed, allowing Taiwan to successfully provide a rapid screening tool for COVID-19 virus using lateral flow chromatographic immunoassay technology.

Q8. Will this test hurt?

No, the nasal swab is not sharp, and the part touching the nasal wall is soft. You can expect some discomfort, but there should not be a sharp pain. Do not insert the swab any deeper if you feel a strong resistance or pain.

Q9. What are the known and potential risks and benefits of this test?

Potential risks include:

Possible incorrect test result (see **Q11**)

You may feel uncomfortable during sample collection.

Potential benefits include:

Slow the spread and help protect the most vulnerable in your families and communities.

The results, along with other information, can help your doctor make informed recommendations for your care.

Q10. What is the limitation of the procedure in this FORA COVID-19 Antigen Rapid Test?

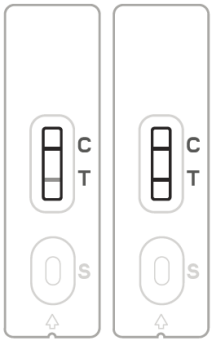
1. The contents in this kit are used for the qualitative detection of SARS-CoV-2 antigens from nasopharyngeal and nasal samples.
2. Do not use any accessory past the expiration date.
3. Users should test samples as quickly as possible after sample collection,

   and please note that all results after **20 minutes** are not valid.
4. Failure to follow the test procedure or incorrect interpretation of results may adversely affect test performance and result.
5. A negative test result may occur when the amount of virus (antigen) in a sample is below the limit or when a test has been conducted incorrectly.

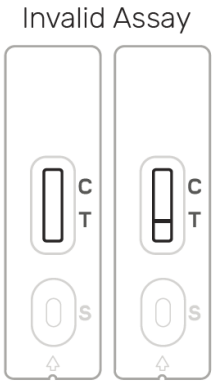
6. Negative results cannot completely rule out the possibility of COVID-19 infection. Negative results must be determined with an FDA authorized molecular assay.
7. The colour of the test line does not correlate with clinical symptoms and severity. The interpretation of the test results must be evaluated together with epidemiology, clinical symptoms, and other diagnostic methods.
8. Positive test results do not rule out co-infections with other viruses.
9. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
10. This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. The test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
11. Test results must be evaluated in conjunction with other clinical data available to the physician.
12. It requires consultation with local public health departments to do additional testing if the differentiation of specific SARS viruses and strains is needed.

Q11. What do the results tell me in FORA COVID-19 Antigen Rapid Test?

Valid Assay:

Positive 	In addition to the presence of the colored C line, if the colored T line also appears, the test result indicates the presence of the SARS-CoV-2 virus in the nasal and nasopharyngeal samples. The result is COVID-19 positive or COVID-19 reactive. Within the specified observation time, a very weak colored line should be judged as a positive result. False positive results may occur due to cross-reacting antigens from previous infections, such as other coronaviruses or other causes. Samples with positive results should be confirmed with a molecular diagnostic test (e.g., RT-PCR) and clinical findings before making any diagnostic determinations.
Negative 	If only the colored C line appears, the test result indicates that the SARS-CoV-2 virus has not been detected. The result is COVID-19 negative or COVID-19 non-reactive. Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or areas with a high prevalence of active infection. Follow-up testing with a molecular diagnostic test (e.g., RT-PCR) is necessary to rule out infection in these individuals.

Invalid Assay:



There should always be a colored control line in the control region regardless of the test result. Repeat the assay with a new test cassette if the control line does not appear.

Negative / High CT value:

Within a specified observation time, a very weak and faded color on the T line should be judged as a negative high CT value. Please refer to the RT-PCR result.

Q12. What will happen if my test result is positive for COVID-19?

Please follow your local laws to report to the local healthcare authorities where you will be asked to self-quarantine on suggested days.

Generally speaking, you should stay at home for 7 days from the onset of symptoms. If fever persists for longer than 7 days, you should stay at home until you have been symptom-free for 48 hours (other than a dry cough).

You should inform local authorities and follow any additional advice given by them. Everyone in your household should remain self-isolated for 14 days from when you developed symptoms. If they become symptomatic, they will need to continue self-isolating for 7 days from the onset of symptoms.

Q13. What will happen if my test result is negative for COVID-19?

Please follow your local laws to continue or stop self-quarantine measures.

Your local healthcare authorities will advise you on when you can return to work. If you do not feel well enough to work, you must inform your manager, then apply for a non-COVID-related sick leave. Despite the test result being negative, if you/your family member still have significant symptoms, local healthcare authorities will make a clinical judgment to organize a re-test.