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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 the COVID-19 a pandemic on 11 March 2020. COVID-19 has caused millions of confirmed cases worldwide, including hundreds of thousands of deaths, and statistics are increasing. It has been reported that symptoms ranging from mild to severe may appear 2-14 days after exposure to SARS-CoV-2. People with these symptoms may suffer from COVID-19: 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 of them may even develop respiratory failure. In severe cases, the symptoms could progress to severe pneumonia, acute respiratory distress, or multiple organ failure, and shock. According to available epidemiological data reported so far, most patients eventually recover, but there are still some deaths. 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 treatment for COVID-19?

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

- Severe shortness of breath (not being able to talk without gasping for air)
- Continuous pain or pressure in your chest
- Feeling confuse or having difficulty waking up
- Blue-colored lips or face

- Any other emergency signs or symptoms

If you seek medical attention, be sure to call ahead before visiting the facility. This will help the facility keep other people from possibly getting infected or exposed.

- Tell any healthcare provider that you may have COVID-19.
- Avoid using public transportation, ride-sharing, or taxis.
- Put on a facemask before you enter any healthcare facility.

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

It is used on individuals who are suspected of COVID-19 by their healthcare provider. 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 the 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 is designed to detect antigen from the SARS-CoV-2 in fresh nasopharyngeal swabs directly from patients who are suspected of COVID-19 by their healthcare provider. This test allows for the detection of SARS-CoV and SARS-CoV-2. The test detects, but does not differentiate, between the two viruses.

Q6: What are the advantages of the 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 important benefits. They are highly portable, scalable, easy-to-use and provide a flexible approach to helping more people in more places get access to reliable testing in a cost effective way. The 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 fast results in only 15 minutes.

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

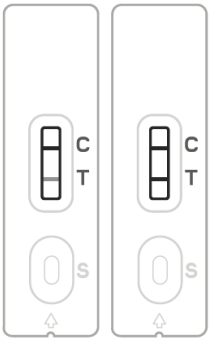
Q7: How accurate is the FORA COVID-19 Antigen Rapid Test?

According to the literature of Target Product Profile Point of Care SARS-CoV-2 detection tests, the acceptable 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%.

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

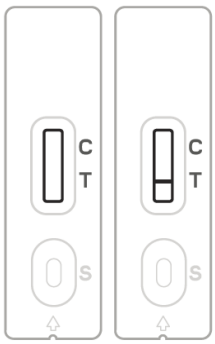
Q8: What do the results mean in the FORA COVID-19 Antigen Rapid Test?

Valid Assay:

Positive 	In addition to the presence of the colored C line, if the coloured T line appears, the test result indicates the presence of SARS-CoV-2 virus in the nasopharyngeal swab sample. The result is COVID-19 positive or COVID-19 reactive. Within the specified observation time, a very weak coloured 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 from other causes. Samples with positive results should be confirmed with a molecular diagnostic test (e.g. RT-PCR) and clinical findings before a

	diagnostic determination is made.
Negative 	If only the coloured C line appears, the test result indicates that SARS-CoV-2 virus is not detected at the time when the nasopharyngeal swab sample was collected. 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 in areas with 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:

Invalid Assay 	There should always be a coloured control line in the control region regardless of the test result. If the control line is not seen, repeat the assay with a new test cassette.

Uncertainty:

Uncertainty 	If the amount of virus (antigen) is very low or the test is non-reactive, the test result may show a very weak test line. It is recommended to collect a fresh nasopharyngeal swab sample from the patient again and retest with a new test cassette.

Q9: What will happen if my test result is positive for COVID-19?

Please report to local healthcare authorities in accordance with local laws and put yourself in quarantine for the suggested days.

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

You should inform your local authorities and follow any additional advice given by them. Everyone in your household should remain self-isolating 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.

Q10: What will happen if my test result is negative for COVID-19?

Please follow your local laws to continue or end self-isolation or quarantine.

Basically, you will be advised by your local healthcare authority that you can return to work providing you are well enough to do so. If you do not feel well enough to return to work you must advise your line manager and normal sickness absence procedures will then apply for non-COVID related sickness. If, despite the test result being negative, you/your family member still have significant symptoms, your local healthcare authority will make a clinical judgement regarding organising a repeat test.

Q11: What is the limitation of the procedure of the FORA COVID-19 Antigen Rapid Test?

1. The contents in this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasopharyngeal swab.
2. Failure to follow the test procedure or incorrect interpretation of results may adversely affect test performance and result in invalid interpretation.
3. 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.

4. A negative test result may occur if the amount of virus (antigen) in a sample is below the limit of the assay or if the sample was not collected properly.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. The colour of the test line has no correlation with clinical symptoms and severity. The interpretation of the test results must be evaluated together with epidemiology, clinical symptoms, and other diagnostic methods.
7. Positive test results do not rule out co-infections with other viruses.
8. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Negative results cannot completely rule out the possibility of COVID-19 infection. The possible cause is that the amount of virus (antigen) in the sample is too low to be detected or the sample is not collected properly. Negative results must be determined with an FDA authorized molecular assay.
10. Users should test samples as quickly as possible after sample collection.
11. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with local public health departments, is required.