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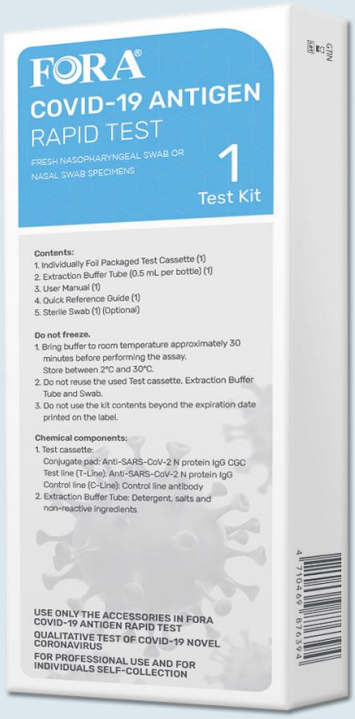
FORA COVID-19 Antigen Rapid Test FAQ



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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 for the 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, 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, 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
- Confusion or difficulty waking up
- 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, carpooling or taxis.
- Put on a facemask before you enter any healthcare facility.

Q4. What is 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 or fresh nasal swab specimens 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.

Q5. Who are the target users of the FORA COVID-19 Antigen Rapid Test?

It should be used on individuals who are suspected of COVID-19 by their healthcare provider or individual.

(1) Trained clinical laboratory personnel:

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.

(2) Self-testing

The test also provides individuals with the option to self-collect nasal samples with the guidance of a healthcare professional. It could also be used without a healthcare professional depending on local regulatory requirements.

Self-collection is suitable for the following people:

- Adults ages 18+ with assistance if needed.

- Adolescents aged 12 – 17 with adult supervision. The adult may conduct the test if needed.
- Children under 12 (Children under 12 years of age should be tested by an adult. Do not conduct this test if you do not feel confident testing a child. Do not continue the test if the child feels any pain).

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.

The 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 94.2% and 99.6%, which meets the acceptance criteria (sensitivity≥ 80% and specificity≥ 95%).

Q8: What is the difference between the two options of the FORA COVID-19 Antigen Rapid Test?

	Antigen Test (Single Packed)	**Antigen Test (Standard)**
Intended use	Professional use / home use / self-test	Professional use
Packaging contents		
Tests per packaging	1	20
Extraction buffer	1*Extraction buffer tube (0.5mL/tube)	2*Extraction buffer (6mL/bottle)
Tube	-	20* Extraction tube and nozzle cap
Nasopharymgeal / Nasal swabs	1	20
Clinical performance		
Test Principle	Lateral Flow Chromatographic Immunoassay	
Target Antigen	SARS-CoV-2 Nucleocapsid Protein	
Sample Type	Fresh Nasopharyngeal sample (professional) or fresh nasal sample (home use)	
Limit of Detection (LoD)	1.26×10^2 $TCID_{50}$ per mL	
Cross-Reactivity & Interferences	Tested viruses, bacteria and interferences did not cross-react nor interfere with the results	
Specificity	99.6%	
Sensitivity	94.2%	

Q9: What is the testing process for the FORA COVID-19 Antigen Rapid Test?

1. Nasopharyngeal Sample (for healthcare professionals):

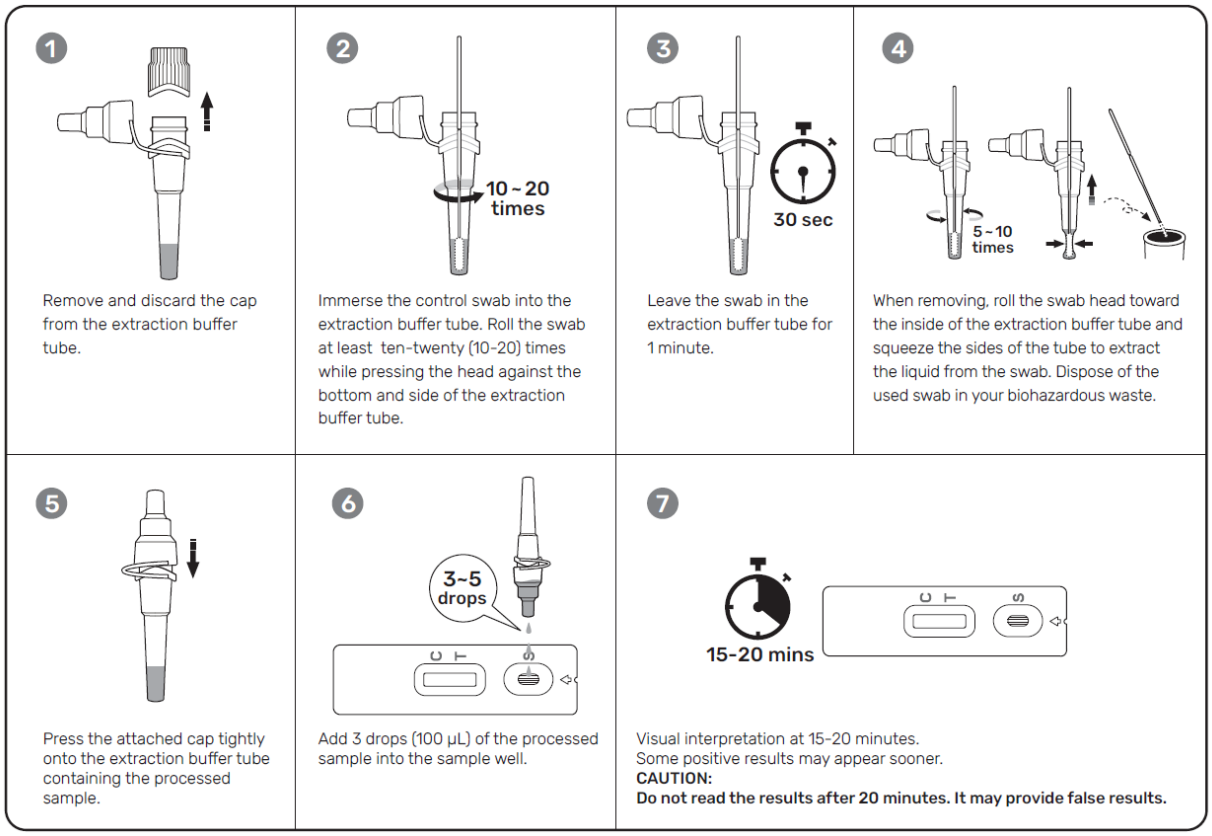
   A. Sample Collection

   a. Use the sterile swab supplied in the kit. Tilt the patient's head back about 70 degrees. To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Gently rotate and insert the swab straight to the palate (not upwards) until resistance is encountered.

   b. Gently rub and roll the swab over the surface of the posterior nasopharynx.

   c. Slowly remove the swab while rotating it.

B. Sample Handling



(2) Nasal Sample (for home use / self-test):

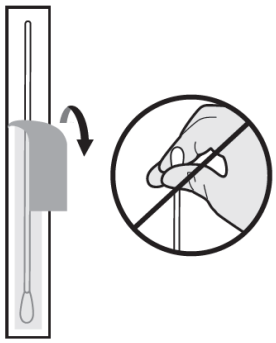
A. Sample Collection

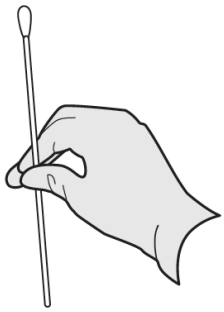
a. Take the test strip out from the sealed packaging and place it on a flat and clean surface. Once opened, start the test within 20 minutes.,

b. Gently blow your nose into a tissue and throw the tissue away in a closed bin. If you are testing a child, help them to blow their nose. This is so that you get rid of excess mucus.

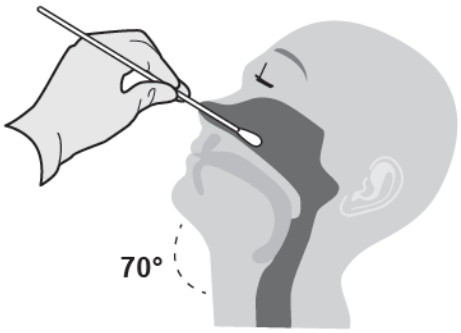
c. Wash your hands thoroughly using soap and water, or hand sanitiser. Dry your hands before performing the test.

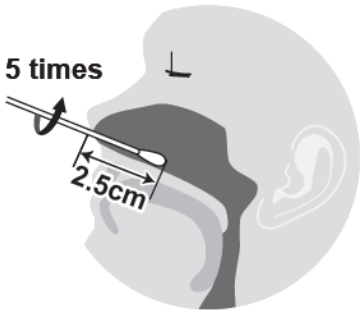
d. Take the swab out. Never touch the soft, fabric tip of the swab with your hands.





e. Tilt the head back about 70 degrees.



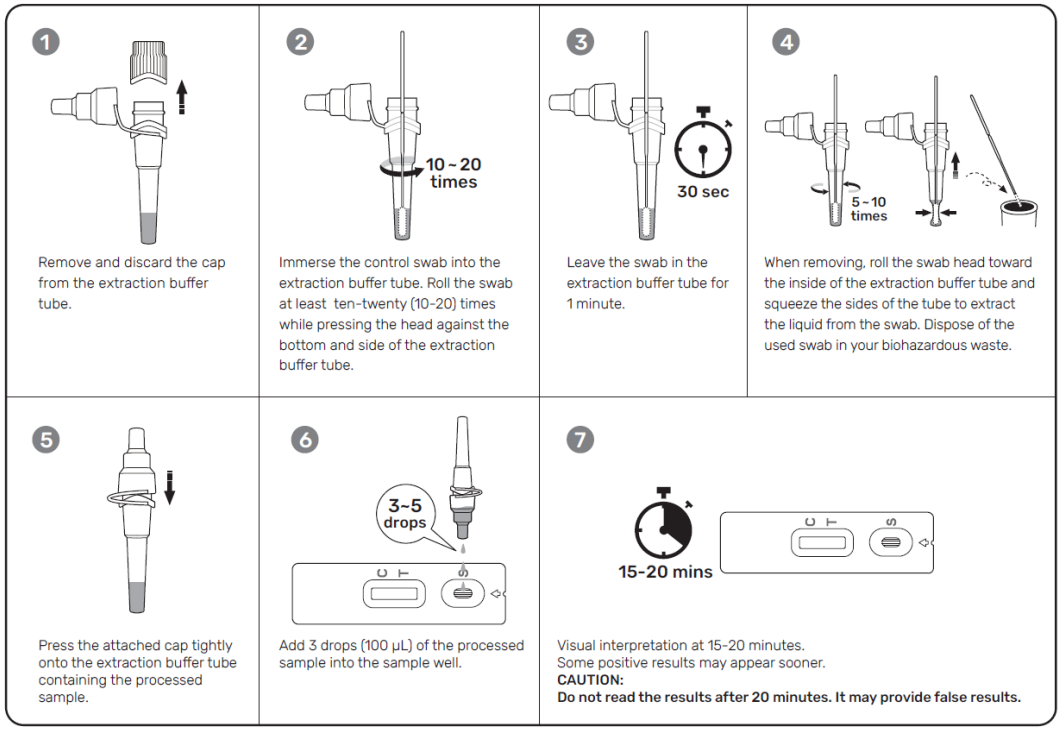


f. Use the sterile swab supplied in the kit to collect a nasal swab sample.

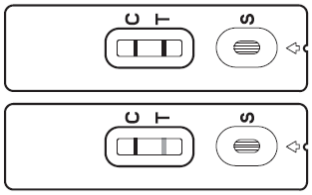
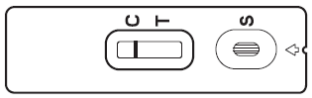
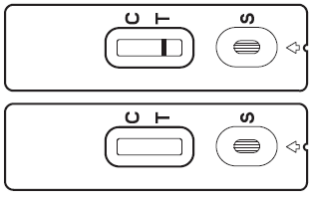
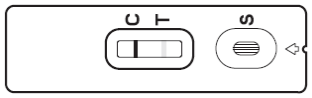
g. Tilt the patient's head back about 70 degrees.

h. Gently insert the entire absorbent tip of the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Gently rotate the swab against the nasal wall for at least 5 times. Make sure the swab tip is touching the nostril walls as you rotate. Take approximately 15 seconds to collect the sample.

B. Sample Handling



Q10: What do the results mean in the FORA COVID-19 Antigen Rapid Test?

	**Positive result** There are two colored liens on the test cassette. Both colored tests and control lines appear on the test cassette. Within the specified observation time, a week colored test line should be judged as a positive result.
	**Negative result** Only the colored control line appears on the test cassette. The absence of the test line indicates a negative result.
	**Invalid result** There should always be a colored control line in the control region regardless of the test result. If the control is not seen, repeat the assay with a new test cassette.
	**Negative / High CT value** Within a specified observation time a very weak colored on T line should be judged as negative or high CT value, please refer to RT-PCR result.

Q11: What will happen if my test result is positive for COVID-19?

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine the status of the infection. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease.

If your test result is positive, you and your household must self-isolate following Government guidelines and call your doctor.

Q12: What will happen if my test result is negative for COVID-19?

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.

That means that you are at this moment negative, but it is only a snapshot. You should still follow hygiene rules, and if you feel sick, please contact your doctor.

Q13: What will happen if my test result is unclear for COVID-19?

(1) For self-individual testing:

When a test does not produce a clear result, please repeat the test again.

(2) For healthcare provider:

It is important that you work with your doctor to help you take further steps if the result is unclear.

Q14: Can the test be used after it is expired?

No, do not use any accessory past the expiration date.

Q15: Can the results be read after 20 minutes?

No, all results after 20 minutes are not valid.

Q16: 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 the 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 immediately 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.

Q17: What is sensitivity?

Sensitivity, also referred to as true positive rate (TPR), represents the antigen tests' proportion of samples that are correctly identified as positive cases. The remaining rate is called false negative rate (FNR), which are the tests that results in a false negative result.

For example, the sensitivity of the FORA COVID-19 Antigen Rapid Test is 99.6%. This means that there is very little cross-reactivity with other coronaviruses, and 0.4% chance to present false negative results due to external influences.

Q18: What is specificity?

Specificity, also referred to as true negative rate (TNR), represents the antigen tests' proportion of samples that are correctly identified as negative cases. The remaining rate is called false positive rate (FPR), which are the tests that results in a false positive result.

For example, the specificity of the FORA COVID-19 Antigen Rapid Test is 94.2%. This means there is a 5.8% chance to present false positive results due to external influences.

Q19: How to avoid false positive and false negative results?

The FDA reminds clinical laboratory staff and health care providers of the risk of false positive and false negative results with all laboratory tests. Laboratories should expect some false positive and false negative results to occur even when very accurate tests are used for screening large populations with a low prevalence of infection.

Healthcare Professionals:

Health care providers and clinical laboratory staff can help ensure accurate reporting of test results by local authorized instructions for use of a test and key steps in the testing process as recommended by the Centers for Disease Control and Prevention

(CDC), including routine follow-up testing (reflex testing) with a molecular assay when appropriate.

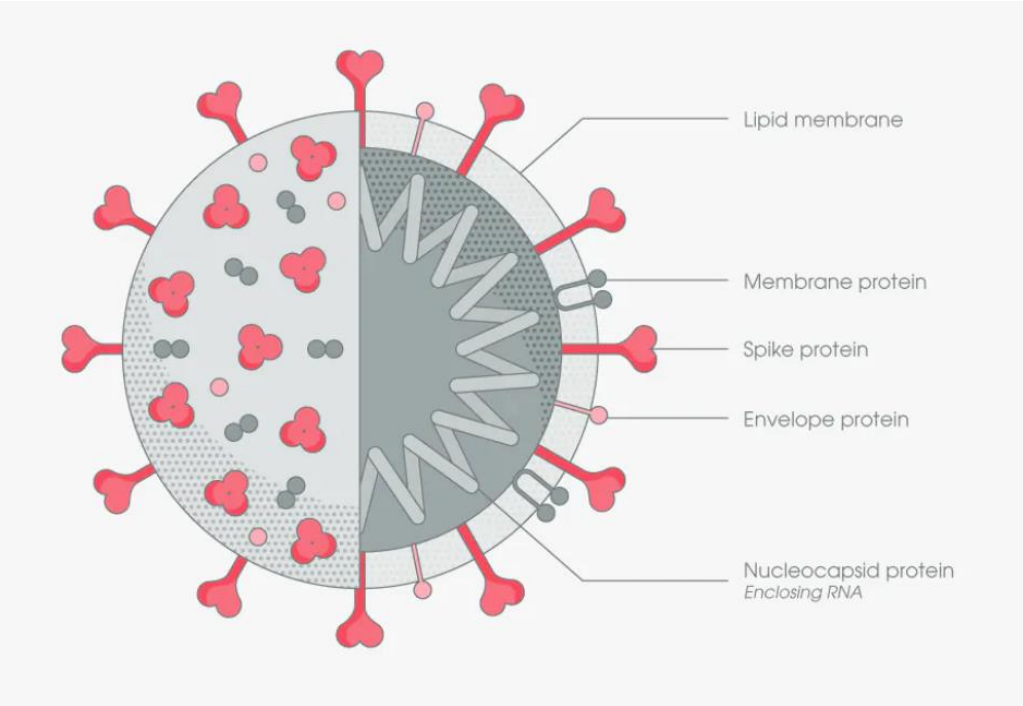
- Be careful to minimize the risks of cross-contamination when testing patient specimens, which can cause false positive results. Please change gloves and clean the work area between specimen handling and processing.
- Consider the CDC's recommendations when using antigen testing in nursing homes and other settings. For positive results, especially in low-incidence counties, consider performing a confirmatory RT-PCR test within 48 hours.

Home Use:

- Follow the manufacturer's instructions for use.
- Do not read the test before or after the specified time. This could result in false positive or false negative results.
- Make sure to collect the sample from both nostrils using the same test swab
- If necessary, follow-up with your healthcare professional to perform a confirmatory RT-OCT test

Q20: Is the antigen test sensitive to the new COVID-19 variants from the UK and South Africa?

Antigen tests can detect the SARS-CoV-2 virus by targeting several proteins as below:



The COVID-19 variants recently found in the UK and South Africa have a mutation in the receptor-binding domain (RBD) of the spike protein. However, the FORA® COVID-19 Antigen Rapid Test targets the nucleocapsid protein to detect SARS-CoV-2, so our antigen test detection capabilities remain sensitive to the new virus mutation.

Q21: What is Cycle Threshold (Ct)?

Cycle Threshold indicates how much virus an infected person has in his or her body. Generally speaking, when Ct>30, the virus quantity is already very low in a person's body. In these situations, the person is unlikely to be contagious, and also it is harder for either PCR and antigen tests to detect whether the person is tested positive or negative due to the low virus quantity.

When testing on a person with Ct>30, the antigen may show a lighter T line, indicating that the patient is most likely infected.