

COVID-19 **ANTIGEN SELF TEST**





INSTRUCTION FOR USE

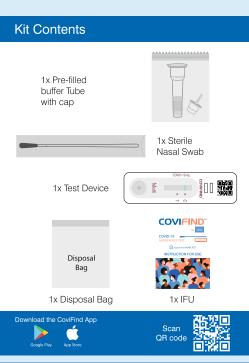


INTENDED USE:

COVIFIND COVID-19 Antigen Self-Test is an In-Vitro diagnostics immunochromatographic rapid assay kit for the qualitative detection of SARS-CoV-2 specific antigen in nasal swab specimens from symptomatic & asymptomatic individuals. This test is authorised & intended for nonprescription home use as self-test with the self-collected nasal specimens from individuals aged 18 years or older & with adult collected nasal specimens from individuals aged 2 years or older. This test intended to be used as an aid in the diagnosis of SARS-CoV-2 infections. A positive test result should be considered as a true positive & does not need reconfirmation by RT-PCR test. Negative results must be combined with clinical observations, patient history, and epidemiological information. Symptomatic individuals identified negative by Rapid Antigen Test (RAT) should be linked with RT-PCR test facility and subsequently get tested by RT-PCR to rule out COVID-19 infection. In the meantime, such individual will be urged to follow home isolation and treatment as a negative report on RAT may not be true negative in some cases.

PRINCIPLE

COVIFIND COVID-19 Antigen Self-Test is an immunoassay kit for rapid and qualitative determination of SARS-CoV-2 infection from swab specimens. Monoclonal anti-SARS-CoV-2 nucleocapsid antibody is coated on the test line region. Antigens of SARS-CoV-2 in the specimens react with the anti-SARS-CoV-2 monoclonal nucleocapsid antibody coupled with gold conjugate, and form an antigen-antibody complex followed by reaction with anti-SARS-CoV-2 monoclonal nucleocapsid antibodies immobilized in the test line. This complex migrates on the membrane, where it will be captured by the monoclonal anti-SARS-CoV-2 antibody. A coloured test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of coloured test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS- CoV-2 antigens are not present in the specimen. then no line appears in the test line. The control band is used for procedural control and should always appear if the test procedure is performed correctly.



Test Preparation



Remove the test components from the box and place them on a flat surface.



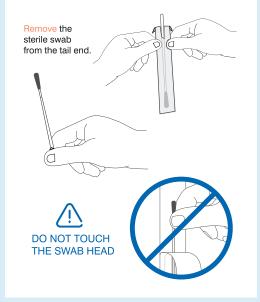




Open the COVIFIND App and fill in the credentials (*All the fields are mandatory as per ICMR guidelines)









Carefully insert the swab into one nostril 2-4 cm or until resistance is met.



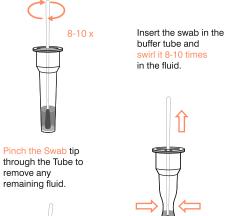


Slowly rotate the Swab, gently rubbing it along the insides of your nasal passage at least 5 times.



Using the same swab, repeat in the other nostril.

Sample Collection: Step 3



Hold the buffer tube firmly, lift the swab till breakpoint and snap the swab handle at breakpoint.



Run Test

Squeeze 4 drops of fluid from the tube into the sample well of the test device.



(*The test device should be immediately used once opened)

Start Timer

You can read the results at 15 minutes.

Results post 20 minutes should not be considered valid.



Click a photo of the Test device on the App. The App will analyse and display your Covid-19 test result and the same shall be final result.

Read Result

Positive Result

If both the Control line "C" and the Test line "T" appear, the result is Positive.





Look very closely! Even a faint line at the bottom indicates a positive result.

Different possibilities of positive result











Note: All Individuals who test positive may be considered as true positives and no repeat testing is required. All test positive individuals are advised to follow home isolation and care as per the ICMR & Ministry of Health & Family Welfare (MoH&FW) protocol which can be accessed at: https://www.fumc.gov.ir/chomeeare.html

Negative Result

If there is only control line "C" and no test line "T" visible, the result is Negative.



Note: All symptomatic individuals who test negative by RAT should get themselves tested by RTPCR. This is especially important as the RATs are likely to miss few positive cases presenting with a low viral load. All RAT negative symptomatic individuals may be treated as suspect COVID-19 cases and are advised to follow ICMR/MoH&FW home isolation protocol while awaiting the RTPCR test result.





Invalid Result

If the control line "C" is not visible, the result will be Invalid regardless of whether test line "T" is visible. In this case repeat the test with a new kit.

Disposal of Test Kit

Place the swab, tube and test device into the disposal bag.







Seal the disposal bag and Dispose the bag in a waste bin.

Disposal bag provided along with the kit provides high level of biocontainment.

The swab inserted in extraction buffer tube which lyse and deactivates the SARS-CoV-2 virus. This tube with broken swab head inside, along with the other components of the test should be put inside the waste disposal bag and thrown in the household waste. Disinfect all surfaces that the specimen may have touched and wash your hands after disposal.

*Discard as per the guidelines for Handling, Treatment, and Disposal of Waste Generated during Treatment/Diagnosis/ Quarantine of COVID-19 patients issued by Central Pollution Control Board.

FAQs

1. Does this test hurt?

The nasal swab may cause slight discomfort. It is important to follow the nasal swab collection steps as indicated in the procedure. Discomfort may occur if the swab is inserted beyond the recommended depth. If painful, slightly withdraw the swab to finish the sample collection process.

- 2. What is the best time to read the results?
- 3. What are the potential benefits and risks of this test?

The test can determine if you have an active COVID-19 infection. The results, along with other information, can help your healthcare provider make informed decisions about your teatment.

You can help limit the spread of COVID-19 by knowing your infection status and taking appropriate social distancing measures

Possible risks:

Slight discomfort during the nasal sample collection.

Possible false test results may occur, if symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor.

4. What are the differences between a COVID-19 Molecular, Antigen and Antibody test?

There are three main types of COVID-19 tests. Molecular tests (also known as PCR tests) detect the genetic material of the coronavirus. The Covifind™ COVID-19 Antigen Self-Test is an antigen test. Antigen tests detect coronavirus proteins. Antibody tests detect antibodies produced by your body's immune system in response to a previous COVID-19 infection. Antibody tests cannot be used to diagnose an active COVID-19 infection.

Test Limitations

- COVIFIND COVID-19 Antigen Test is in vitro diagnostic test, designed for the qualitative detection of SARS-CoV-2 antigen, as self-test at home
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative or non-reactive test result does not preclude the possibility of exposure to or infection with SARS-CoV-2 virus at any time.
- The test for the detection of SARS-CoV-2 antigen should be done in human nasal swab specimens only.
- Failure to follow the test procedure and interpretation of test results may adversely affect the test performance and/or produce invalid results.
- Positive test results do not exclude co-infections with other pathogens while Negative test results do not include other corona virus infection except the SARS-CoV-2.



Scan QR Code For Video Instructions
On How To Use COVIFIND At Home



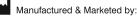














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