

By Meri

COVID-19 — ANTIGEN SELF TEST





## INFORMATION FOR USE



#### INTENDED USI

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 non-prescription 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 intigens 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.

## **Kit Contents**

1x Pre-filled buffer Tube with cap





1x Test Device



COVIFIND





1x IFU

Download the COVIFIND App





Scan QR code

## **Test Preparation**

### Wash your hands.

Make sure they are dry before starting the test.



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)



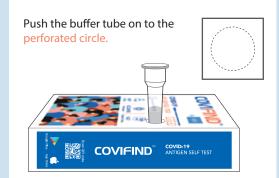


Remove the test device from the pouch.



Peel the Aluminium foil from the pre-filled buffer tube.





# Sample Collection: Step 1







## Sample Collection: Step 2

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 Insert the swab in the

buffer tube and swirl it 8-10 times in the fluid.





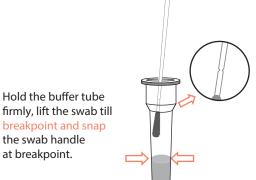
Hold the buffer tube

breakpoint and snap

the swab handle

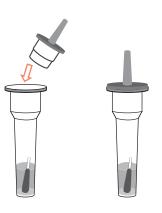
at breakpoint.

Pinch the Swab tip through the Tube to remove any remaining fluid.





Secure the cap on top of the buffer tube.



### **Run Test**

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



(\*Do not leave the test device unused once opened for a longer duration)

### You can read the results within 15 minutes.

Strong positive results will start appearing between 5-10 minutes.

A negative result can be determined at 15 minutes. Results post 20 minutes should not be considered valid.



Click a photo of the Test device on the App for result interpretation.



## **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 possibities 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.icmr.gov.in/chomecare.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.





# 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 the Lysis buffer tube kills SARAS-CoV-2 & other viruses. 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.

















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