

COVIatHOME™

By PATHKITS

Coronavirus Test (COVID-19) Antigen Self Test Kit (Single Kit)



Intended Use:

PATHKITS COVIatHOME COVID-19 Antigen Self-Test is intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens from anterior nasal secretion from individuals suspected of COVID-19 by their healthcare provider, having covid-19 symptoms as per ICMR guidelines and was in contact with a COVID-19 Positive individual. This test kit can be used without prescription at home as a self-test with 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 is intended to be used for the purpose of self detection 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 refer to an ICMR approved COVID testing Lab for RT PCR Test. In the meantime, such individuals will be urged to follow home isolation and treatment as a negative report on RAT may not be true negative in some cases.

Principle

PATHKITS COVIatHOME COVID-19 Antigen Self-Test Kit is an immunochromatography assay which detects SARS-CoV-2 nucleocapsid antigen in the samples with the help of double antibody sandwich method. If there is a virus antigen present in the sample, it binds with the corresponding colloidal gold antibody. This complex "migrates" across the membrane and binds to the monoclonal antibody at the Test line (T). This creates a visible Red Line, which indicates a positive result. However if the sample does not contain the antigen, then the complex cannot be formed and thus no reddish line forms in the Test Line (T). Regardless of whether the sample contains antigen or not, a reddish line forms in the control line (C), to confirm the test is complete.

Storage Conditions

Store in cool, dry places, away from direct sunlight and humidity. Keep the kit out of reach of children.

KIT COMPONENTS



Download Pathkits
COVIatHOME COVID-19 Ag test
app from Play Store/App Store.



Test Preparation

Wash your hands,

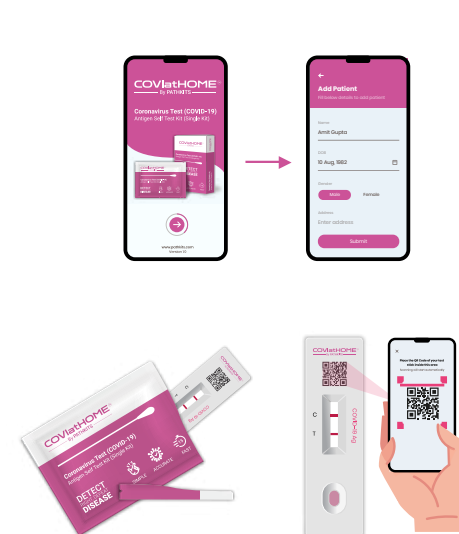
Make sure they are dry before starting the test procedure.



Tear the pouch and keep the individual components ready for the testing.



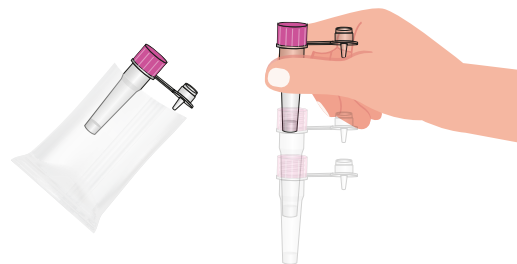
Open the Pathkits COVIatHOME Covid-19 app and fill-in credentials, (*All fields are mandatory as per ICMR guidelines.)



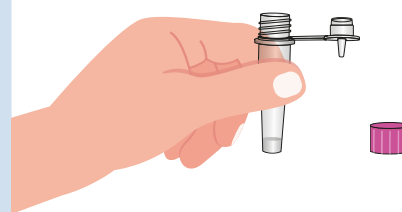
Open the pouch containing the test device, (Cassette)

Scan the QR Code on the cassette to link the code with your credentials.

Find the pre-filled buffer tube and remove it out of the pouch and tap vertically on the horizontal surface, to make sure that the extraction buffer settles at the bottom of the tube.

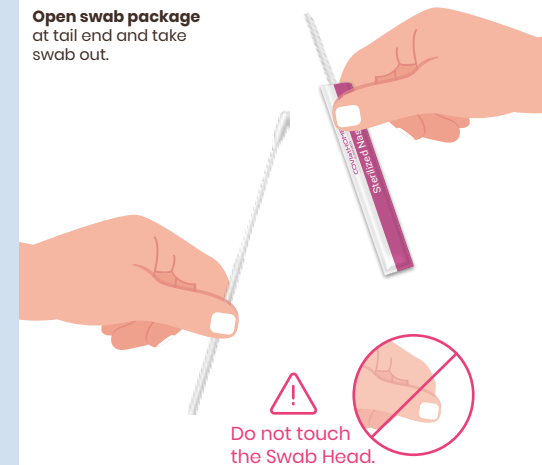


Remove the cap and hold the tube in your hand. Do not spill the content of the tube.

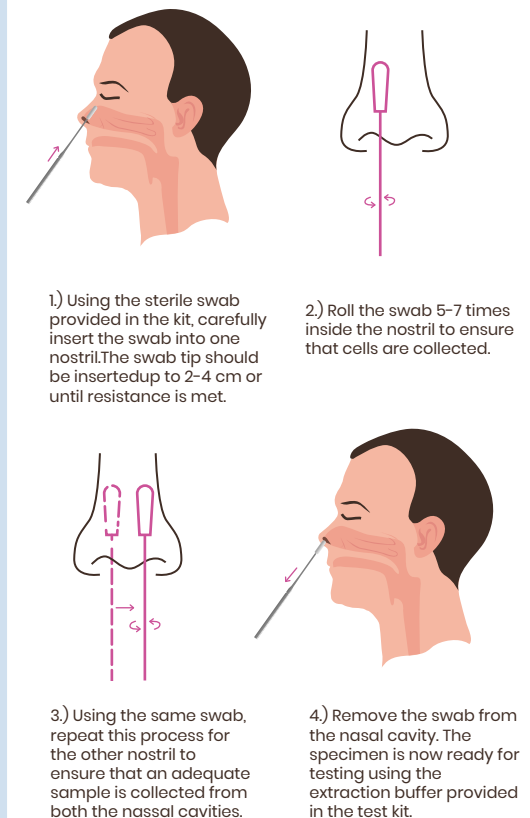


Step 1

Open swab package at tail end and take swab out.

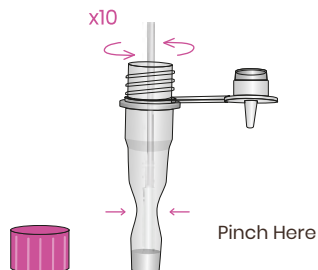


Sampling with a nasal swab

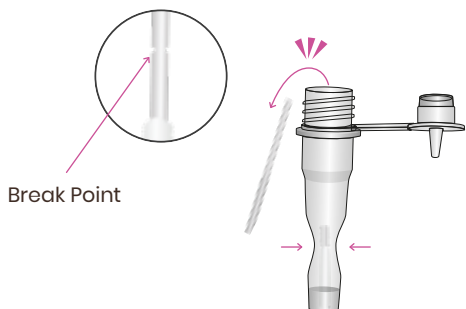


Step2

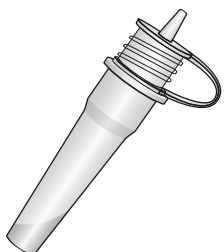
Take the nasal swab and dip in the pre-filled extraction tube. Pinch the tube at the bottom and swirl nasal swab 10 times ensuring the swab is immersed well in the extraction buffer.



Find the Breakpoint of the swab. Break the swab at the breakpoint. Discard the remainder of the swab. Mix well.



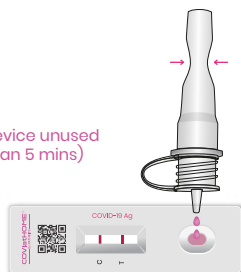
Cover the tube with attached nozzle cap and tighten the lid.



Step3

Add 3 full drops of extraction antigen buffer mixture into the sample well of the test device, by pressing the tube, and wait for 10-15 mins for the results to appear.

(*Do not leave the test device unused once opened for more than 5 mins)



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.



Mobile App on your Phone will give you the alarm to capture the test result

Step4

Take the test device and click the picture



Wait for the App to analyse and display your Covid-19 Test results.



All components of this kit should be discarded as Biohazard waste according to the local regulatory requirements.

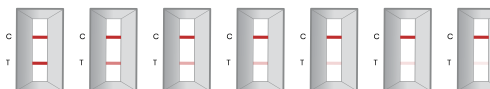
Positive Result

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 positive 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.



Limitations of Test

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of COVID-19 virus in the swab specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may lead to inaccurate results.
2. Sensitivity can differ with various strains of SARS-CoV-2 due to differences of antigen expression. Specimens might contain a new or non-identified strain of SARS-CoV-2 that expresses varying amounts of antigen.
3. A negative or non-reactive result for an individual subject indicates absence of detectable SARS-CoV-2 virus. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.
4. Performance of the test has not been established for monitoring antiviral treatment of SARS-CoV-2 infection.

FAQ

1. Does the virus remain activated in extraction buffer tube ?
The extraction buffer chemicals inactivate the live virus by following lysis reaction methods.
2. Does the mobile app work on iPads and Android Tablets ?
The mobile app is designed to work on both iPads and Android tablets.
3. Can I test multiple times and record results on Mobile App ?
Yes, you can test yourself any number of times and record results on the Mobile app.
4. Can I test my family members or friends and record results for them on my Mobile App ?
Yes, the mobile app supports the feature for you to add more patients to it and record results for those.
5. What happens if I cancel a test in between ?
Once you have scanned the test cassette, then the cassette gets associated with the patient. Even if you cancel the test this cassette cannot be used to record results for a different patient.
6. Can I record results later ?
Yes, in the mobile app you can either do a start test and then scan the QR code of the Cassette you have used to upload your results. If you have already started the test, you can navigate to the screen showing your test results and record the results for a previously started test.



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