Mylab
Discovery solutions

Information For Use

CoviSelf™

COVID-19 Rapid Antigen Test

Self Test Kit

Version 1.0
26 April 2021

mylabdiscoverysolutions.com

INTENDED USE

The CoviSelf™ COVID-19 Rapid Antigen Test (RAT) is an *in vitro* diagnostic test for the qualitative detection of COVID-19 antigen in nasal swab specimens directly from individuals with or without symptoms or with other epidemiological reasons to suspect COVID-19. This test is authorized for non-prescription home use with self-collected nasal swab specimens from individuals aged 18 years and older or with adult-collected samples from individuals aged 2 years or older.

For Negative Test: Symptomatic individuals identified negative by 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.

For Positive Test: A positive test should be considered as a true positive and does not need reconfirmation by the RT-PCR test.

Read the instructions before performing the test. All tests should be conducted by the individuals with own consent and completely at own risk, cost and consequences.

KIT STORAGE AND STABILITY

1. You can store the testing kit at room temperature in a place out of direct sunlight and out of reach of children.
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after the expiration date.

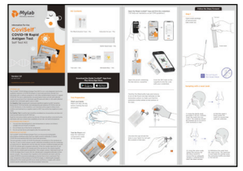
PRINCIPLES OF THE TEST

The CoviSelf™ COVID-19 Rapid Antigen Test is an immunochromatographic nitrocellulose membrane assay that uses highly sensitive antibodies to detect COVID-19 nucleocapsid protein from nasal swab specimens.

The test assembly consists of COVID-19 antibodies immobilized on the membrane as Test line (T) and a control solution specific antibodies immobilized onto the membrane as Control line (C). Besides this, the test strip also contains a buffered sample pad with COVID-19 colloidal gold conjugated antibodies. When the sample (specimen & Lysis buffer mixture) is added to the sample pad of the test device, the sample migrates along with the colloidal gold nanoparticles. If the sample contains 'detectable levels" of COVID-19 antigen then it reacts with the colloidal gold conjugated antibodies to from Ag-Ab complex. This complex then migrates to the membrane and reacts with the coated COVID-19 monoclonal antibodies on the test line to form a test band (Test Line). Irrespective of the presence of COVID-19 antigen, a colloidal gold conjugate antibody from the sample pad still moves ahead and forms a complex with control solution-specific antibodies to form the procedural Control line.

Kit Contents

Pre-filled Extraction Tube - 1 No.



Instruction for use - 1 No.

Sterile Nasal Swab - 1 No.

Test card - 1 No.

Biohazard Bag - 1 No.

Download the Mylab CoviSelf™ App from Play Store/App Store.

GET IT ON Google Play | Download on the App Store

Test Preparation

Wash your hands.
Make sure they are dry before starting the test procedure.

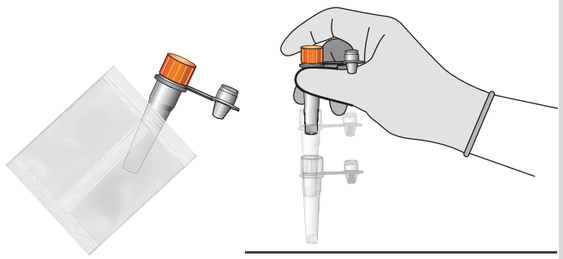
Tear the Pouch and keep the individual components ready for the testing.

Open the Mylab CoviSelf™ App and fill-in the credentials.
(*All fields are mandatory as per ICMR guidelines.)

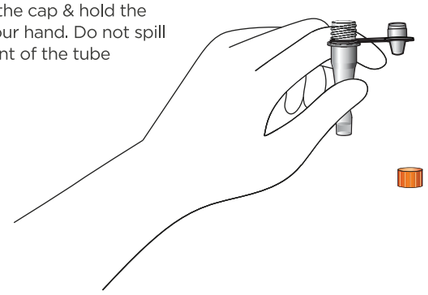
Open the pouch containing the test device. (cassette)

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



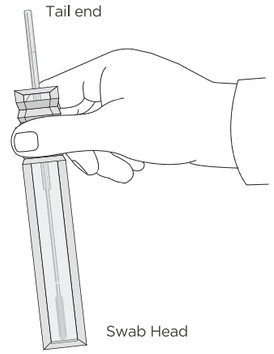
Unscrew the cap & hold the tube in your hand. Do not spill the content of the tube

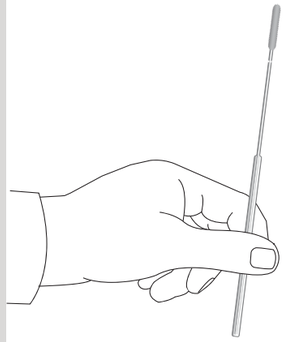


Follow the Steps Forward

Step 1

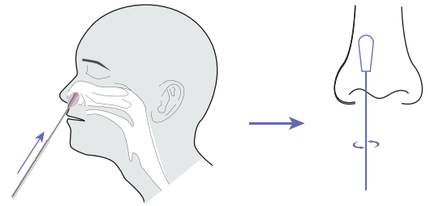
Open swab package at tail end and take swab out.





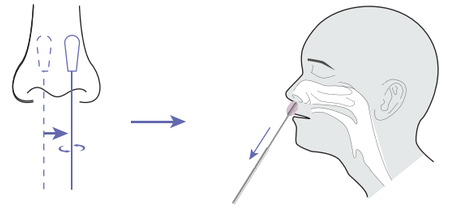
Do not touch the Swab Head.

Sampling with a nasal swab



1) Using the sterile swab provided in the kit, carefully insert the swab into one nostril. The swab tip should be inserted up to 2-4 cm or until resistance is met.

2) Roll the swab 5 times inside the nostril to ensure that cells are collected.

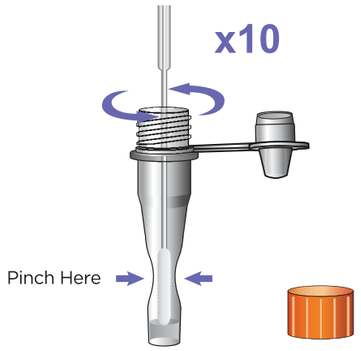


3) Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both the nasal cavities.

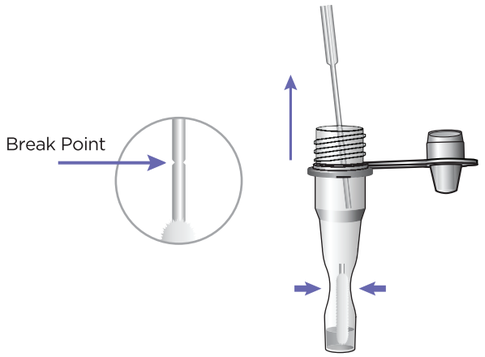
4) Withdraw the swab from the nasal cavity. The specimen is now ready for testing using the extraction buffer provided in the test kit.

Step 2

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



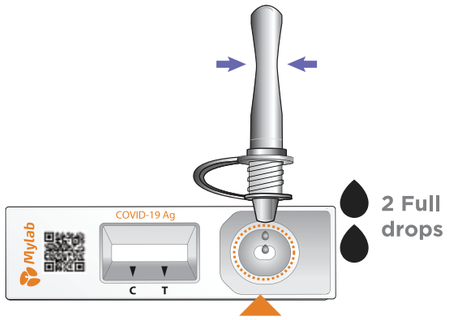
Find the Breakpoint of the swab. Break the swab at the breakpoint. Discard the remainder of the swab. Mix well.



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

Step 3

DO NOT leave the test device unused once opened for more than 5 minutes. **Add 2 full drops** of extracted 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

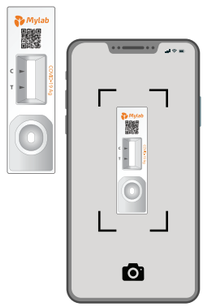


Read the results within 20 minutes. Strong positive results can be reported within 10-15 minutes. However, wait up to 20 minutes to report negative results. Results that appear after 20 minutes are not valid.

Phone will give you the alarm to capture the test result

Step 4

Take the test device and click the picture



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

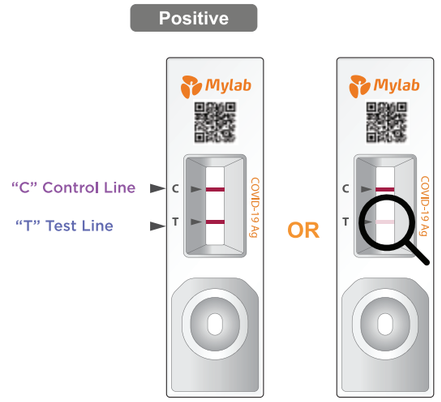
Biohazard bag provided along with the kit provides high level of biocontainment

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

*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

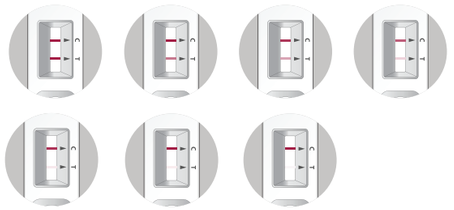
Positive Result

If both the quality control line "C" and the detection line appear, novel coronavirus antigen has been detected and the result is positive for antigen.



Look very closely! The bottom line can be very faint. Any pink/purple line visible here indicates a positive result.

Different Possibilities of Positive Result



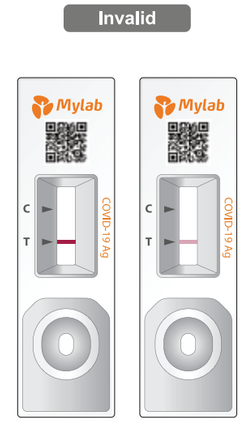
NOTE: Positive result indicates the presence of COVID-19 virus in the sample. It is important to be under the care of your healthcare provider. You should be placed in isolation to avoid spreading the virus to others. Your healthcare provider will work with you to determine how best to care for you based on your test result along with your medical history, and your symptoms.

Negative Result

If there is only a quality control line "C", and no test line "T" it indicates that the result is negative.

Invalid

If the quality control line "C" is not observed, it will be invalid regardless of whether there is detection line "T"



FAQ

1. What are the known and potential hazards and benefits of this test?

No Potential hazard is associated with the test, however there might be

- Possible discomfort during sample collection.
- Possibility to interpret incorrect test results (see results section).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

2. Will this test hurt?

No, the nasal swab is specially designed by Mylab which is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

3. Difference between an antigen and molecular test?

Molecular tests (also known as RT-PCR tests) detect the genetic material of the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation.

Limitation Of The Procedure

1. This reagent is only used for *in vitro* diagnosis.
2. This reagent is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and produce an invalid result.
5. A negative result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
6. Positive results, do not rule out co-infections with other pathogens.

Scan for a video demonstration of how to use the kit
*IOS: Scan from a normal camera.
Android: Scan through any QR code scanner app.

Mylab Discovery solutions

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