**Information For Use**

**CoviSelf™ COVID-19 Rapid Antigen Test**

**Self Test Kit**

**Version 1.0**

26 April 2021

www.coviself.com

**INTENDED USE**

The CoviSelf™ COVID-19 Rapid Antigen Test (RTAT) 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 nonprescription home use with self-collected nasal swab specimens from individuals aged 18 years and older or with adults-collected samples from individuals aged 2 years or older.

For Negative Test: Symptomatic individuals identified negative by RAT should be quarantined and subsequently get tested by RT-PCR to rule out COVID-19 infection. In the meantime, such individual will be advised 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. Affirmative results conducted by the individual with own consent and compliance at own risk, cost and consequences.

**KIT STORAGE AND STABILITY**

1. 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 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 nitrilotriacetic acid 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 line specific antibodies immobilized onto the membrane as Control Line (C). Besides this, the test strip also contains a buffered sample pad with COVID-19 nucleocapsid protein antibodies. When the sample (specimen & lysate 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, a colloidal gold conjugate antibody from the sample pad will move ahead and form a complex with captured line-specific antibody to form the procedural Control Line.

**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 3-4cm 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 nasal cavities.
4. Withdraw the swab from the nasal cavity. The specimen is now ready for testing in the extraction buffer provided in the test kit.

**Kit Contents**

- Pre-filled Extraction Tube × 1 No.
- Instruction for use × 1 No.
- Sterile Nasal Swab × 1 No.
- Test card × 1 No.
- Disposable Bag × 1 No.

**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.
**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.

**Step 4**
Take the test device and click the picture. Wait for the app to analyze and display your Covid-19 Test results.

Swab is inserted in the lysis buffer tube which allows COVID-19 and other viruses. This tube with broken swab head inside, along with other components of the test, should be put inside the disposable bag and thrown in the household waste. Disinfect all surfaces that the specimen may have touched, and wash your hands after disposal.

**Step 3**
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.

**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.

**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 Prolongable risk is associated with the test, however, there might be:
     - Possible discomfort during sample collection.
     - Possible by incorrect (incorrect test results) due to:
       - Potential benefits include:
         - The results, along with your information, can help your healthcare provider make informed recommendations about your care.
         - The results of this test may help predict the spread of COVID-19 to your family and others in your community.

2. Will I return both tests?
   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 tickle. If you have any issue, stop the test and seek advice from your 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.

4. How can I share the results?
   Scan for a video demonstration of how to use the kit.

5. What is NATSpert?
   NATSpert is a rapid antigen test for COVID-19.

**ICMR Guidelines**
- All individuals who test positive may be considered 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 (MoHFW) protocol which can be accessed at: [https://www.icmr.gov.in/chroma-cars.html](https://www.icmr.gov.in/chroma-cars.html)

**Limitation Of The Procedure**
1. This test is not used for in vitro diagnosis.
2. This test is not used for qualitative detection and cannot indicate the level of neutralizing antibodies in the specimen.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and produce an invalid result.
4. A negative result may occur if the level of antigen exceeds the amount detectable by the test.
5. Positive results do not rule out co-infections with other pathogens.

**Manufactured & Marketed by**: Mylab Discovery Solutions Pvt. Ltd., Plot No., 994-8, Lavale, Industrial Co-operative Estate Ltd., Naneghat, Lonavala, Pune, Maharashtra 412041, INDIA.

Email: care@mylabglobal.com
Web: [www.covid19lab.com](http://www.covid19lab.com)
Toll-Free: 1800-121-8884

**PathoDetect | NATSpert | PathoCatch | OncoScreen | DiscoverSeries | AgroDex | VetScreen | Compact XL | **