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COVID Self-Check

Powered by TATA MD

INSTRUCTIONS FOR USE

AbChek COVID-19 Antigen Rapid Home Test Kit

Using **"COVID Self-Check - Powered by Tata MD"** App

INTENDED USE

AbChek COVID-19 Antigen Rapid Home Test Kit is a rapid and convenient immuno- chromatographic assay for the qualitative detection of COVID-19 antigen (viral nucleoprotein) from nasal swab obtained from patients with signs and symptoms of respiratory infection. The device is designed to aid in the rapid differential diagnosis of COVID-19 Virus infection. This assay is intended to be used for screening patients with suspected COVID-19 Ag infection having symptoms of respiratory infections or immediate contact with confirmed positive cases. This assay is intended for home testing (or self- testing). Asymptomatic individuals are not advised to undertake the home test. The test results should be confirmed by Real-Time Reverse Transcriptase (RT-PCR) Diagnostic kit; they do not preclude COVID-19 Virus infection and should not be used as the sole basis for treatment or other management decisions.

All tests should be conducted by the individuals with their own consent and completely at their own risk, cost and consequences, and the test results should be uploaded at the ICMR site using the "COVID Self-Check - Powered by Tata MD" App.

SUMMARY AND PRINCIPLE OF THE ASSAY

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) is the virus strain that caused an outbreak of a novel coronavirus disease (COVID-19), which has subsequently affected countries and regions worldwide. Severe disease onset might result in death due to massive alveolar damage and progressive respiratory failure. On March 11, 2020, the World Health Organization (WHO) has declared the global outbreak of COVID-19 a pandemic associated with substantial morbidity and mortality.

AbChek COVID-19 Antigen Rapid Home Test is an antigen-capture immunochromatographic assay, detecting presence of COVID-19 viral nucleoprotein antigen in nasal swab samples. This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen. COVID-19 monoclonal antibodies specifically against COVID-19 antigen are conjugated with colloidal gold, deposited on the conjugate pad, and immobilized on the Test Zone of the nitrocellulose membrane. When a sample is added, the gold-antibody conjugate is rehydrated and the COVID-19 antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen- antibody-gold complex will migrate towards the test window until the Test Zone where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative a positive result. If COVID-19 antigen is absent in the sample, no pink line will appear in the Test Zone (T). To serve as an internal process control, a control band was designed to indicate that the test is performed properly. To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

CONTENTS

- **Kit Contents:**

POUCH

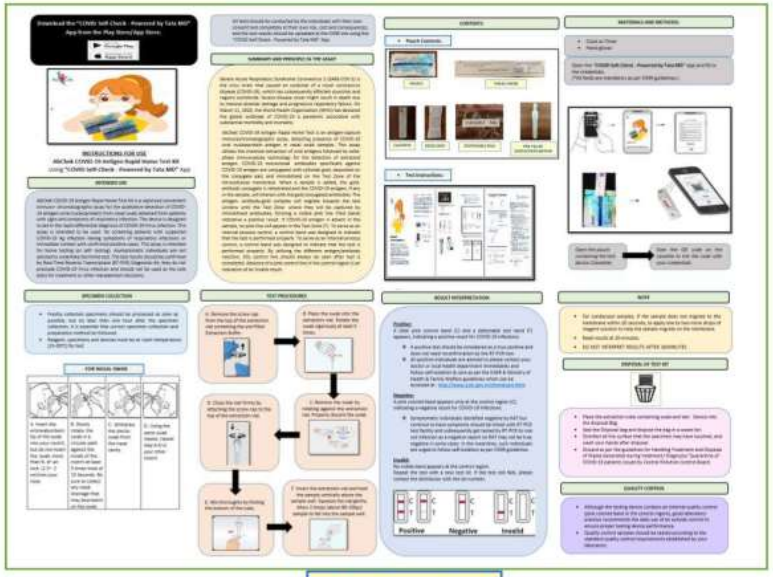
NASAL SWAB

CASSETTE

DESICCANT

DISPOSABLE BAG

PRE-FILLED EXTRACTION BUFFER

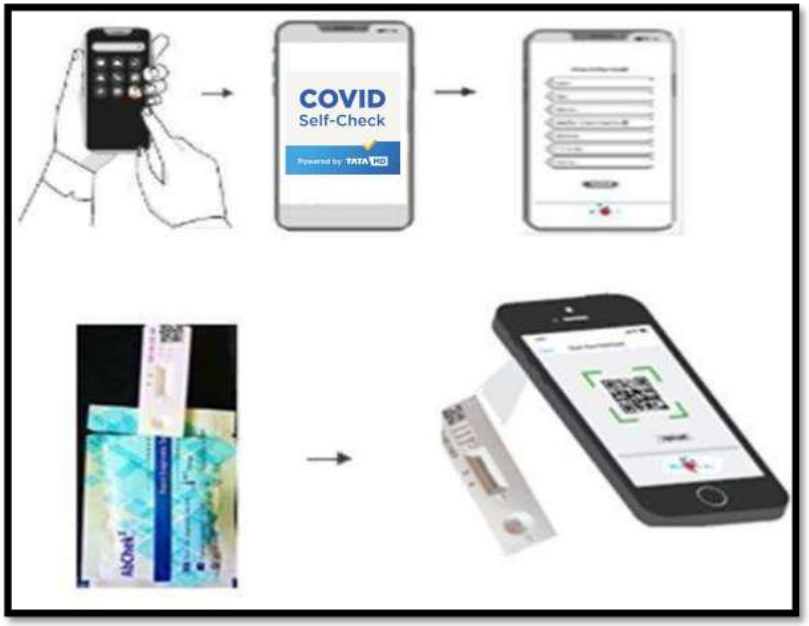


Test Instructions

MATERIALS AND METHODS:

- Hand gloves

Open the **"COVID Self-Check - Powered by Tata MD"** App and fill-in the credentials.
(*All fields are mandatory as per ICMR guidelines.)



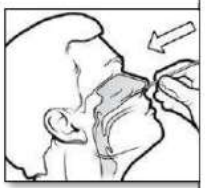
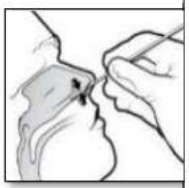
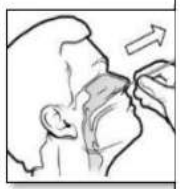
Open the pouch containing the test device (Cassette).

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

SPECIMEN COLLECTION

- Freshly collected specimens should be processed as soon as possible, but no later than one hour after the specimen collection, it is essential that correct specimen collection and preparation method be followed.
- Reagent, specimens and devices must be at room temperature (15-30℃) for test.

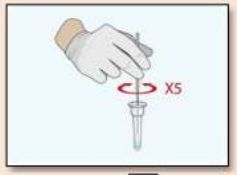
FOR NASAL SWAB

			
A. Insert the entireabsorbent tip of the swab into your nostril, but do not insert the swab more than ¾ of an inch (1.5~ 2 cm)into your nose.	B. Slowly rotate the swab in a circular path against the inside of the nostril at least 5 times total of 15 Seconds. Be sure to collect any nasal drainage that may bepresent on the swab.	C. Withdraw the sterile swab from the nasal cavity.	D. Using the same swab repeat, repeat step A-D in your other nostril.

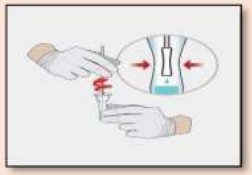
TEST PROCEDURES

A. Remove the screw cap from the top of the extraction vial containing the pre-filled Extraction Buffer.

B. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



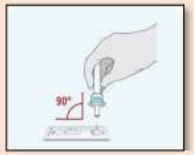
C. Remove the swab by rotating against the extraction vial. Properly discard the swab.



D. Close the vial firmly by attaching the screw cap to the top of the extraction vial.

E. Mix thoroughly by flicking the bottom of the tube.

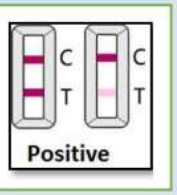
F. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow 2 drops (about 80-100µl) sample to fall into the sample well.



RESULT INTERPRETATION

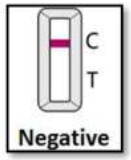
Positive:

- A clear pink control band (C) and a detectable test band (T) appears, indicating a positive result for COVID-19 infections.
- A positive test should be considered as a true positive and does not need reconfirmation by the RT-PCR test.
- All positive individuals are advised to please contact your doctor or local health department immediately and follow self-isolation & care as per the ICMR & Ministry of Health & Family Welfare guidelines which can be accessed at: http://www.icmr.gov.in/chomecare.html



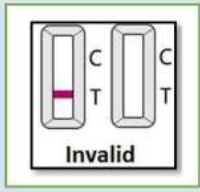
Negative:

- A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 Infections.
- Symptomatic individuals identified negative by RAT but continue to have symptoms should be linked with RT-PCR test facility and subsequently get tested by RT-PCR to rule out infection as a negative report on RAT may not be true negative in some cases. In the meantime, such individuals are urged to follow self-isolation as per ICMR guidelines.



Invalid:

- No visible band appears at the control region.
- Repeat the test with a new test kit.
- If the test still fails, please contact the distributor with the lot number.



NOTE

- For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply one to two more drops of reagent solution to help the sample migrate on the membrane.
- Read results at 20 minutes.
- DO NOT INTERPRET RESULTS AFTER 30MINUTES

DISPOSAL OF TEST KIT

- Place the extraction tube containing swab and test Device into the disposal Bag.
- Seal the Disposal bag and dispose the bag in a waste bin.
- Disinfect all the surface 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.

QUALITY CONTROL

- Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance.
- Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30 ^{0}C up to the expiration date. Test Devise has shelf life of 2 years. Do not freeze thetest device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- The kit is only intended for nasal swab specimens that are collected and tested directly (i.e. Swabs thathave NOT been placed in transport media).
- The kit includes a pre-diluted processing reagent in a ready to use unitized tube.
- The kit is not INTENTED for testing liquid samples such as wash or aspirate samples or swabs intransport media as results can be compromised by over dilution.
- Use in conjunction with the testing strategy outlined by public health authorities in your area.
- Humidity and temperature can adversely affect results.
- The contents of this kit are to be used for the qualitative detection of COVID-19 antigen from nasalswab, nasal wash and nasal aspirate specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of thetest.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect testperformance and/or invalidate the Test Result.
- Negative test results do not rule-out possible other non-COVID-19 viral infections. Positive test results do not rule out co-infections with other pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high.
- False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
- Test-specific limitations, as required.

REFERENCES

- Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization.13 March 2020.
- Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). World HealthOrganization. 16-24 February 2020.
- The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19).Chinese Center for Disease Control and Prevention. CCDC Weekly, 2(8):113-122, 2020.
- A novel coronavirus outbreak of global health concern. Wang C et al. Lancet, 395(10223):470-473,2020

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