AbChek Covid-19 Antigen Rapid Test

INTENDED USE

AbChek COVID-19 Antigen Test is a rapid and convenient immuno- chromatographic assay for the qualitative detection of COVID-19 antigen (viral nucleoprotein) from nasopharyngeal swab obtained from patient 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 not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 Ag infection, this assay is not intended for home testing (or self-testing).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. The test is intended for professional and laboratory use.

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 Test is an antigen-capture immunochromatographic assay, detecting presence of COVID-19 viral nucleoprotein antigen in nasopharyngeal 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. 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.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant
- Extraction Buffer Bottle (includes 15 ml extraction buffer, three per box, 5ml per bottle)
- Reagent Tube with Cap
- Sterilized Nasopharyngeal Swab
- Test Instruction

MATERIALS REQUIRED (BUT NOT PROVIDED)

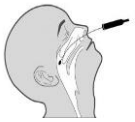
- Pipette
- Clock or timer.
- Latex gloves

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handle.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

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.



1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.

2. Swab over the surface of the posterior nasopharynx.

3. Withdraw the sterile swab from the nasal cavity.

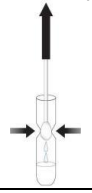
TEST PROCEDURES

A) Add 400ul extraction buffer (approximately 12 drops) into the reagent tube.

B) Add Nasopharyngeal swab to the tube with extraction buffer.

C) Vigorously rotate and twist the swab against the side of the tube at least 10 times.

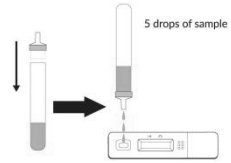
D) Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.



E) Apply the cap to the tubes with specimen, and hold the tube vertically, add 5 drops (about 120 µl) of the specimen without air bubbles into the sample well.

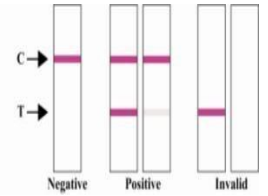
*Note: For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply one to two more drops of reagent solution to help the sample migrate on the membrane.

Read results at 20 minutes.



Note: DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATION



Negative:
A pink colored band appears only at the control region (C), indicating a negative result for COVID-19 Infections.

Positive:
A clear pink control band (C) and a detectable test band (T) appears, indicating a positive result for COVID-19 infections.

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

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 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- The kit is only intended for nasopharyngeal swab specimens that are collected and tested directly (i.e. swabs that have 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 in transport 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 nasopharyngeal swab, 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 the test.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance 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 Health Organization. 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

MANUFACTURER CONTACT INFORMATION

Catalogue No.: NUL/CD-015 **PI No.: QA/COV/21-00**

NuLife
(An ISO 9001:2015 | GMP certified company
D-22/118, Sector-7, Noida, U.P.-201301, India
Tel. : 0120-4351568,
Email : info@nulifecare.in,
Website: www.nulifecare.in