Angcard COVID-19 Antigen Test

ANGSTROM BIOTECH PVT. LTD

Rapid card Test (Immunochromatographic Assay)

INTRODUCTION:

Coronavirus (COVID-19) antigen Kit is a rapid and convenient Immunochromatographic assay for the qualitative detection of COVID-19 antigen (viral nucleoprotein) from nasal swab, nasopharyngeal swab, endotracheal aspirate or bronchoalveolar lavage 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 provides only a preliminary result. Negative 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:

COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered corona virus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. Most estimates of the incubation period for COVID-19 range from 1-14 days.

The COVID-19 Ag, Rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 Present in human nasopharynx. This test is administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection. It provided only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

TEST PRINCIPLE:

COVID-19 Antigen test is an antigen-capture immunochromatographic assay, detecting presence of COVID-19 viral nucleoprotein antigen in nasal swab, 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.

A Kit Contains:

Test card(Individual in a foil pouch with desiccant)
Extraction buffer tube
Nozzle Cap
Sterile Swab
Paper Stand
IFU
The self life or expiry of the card is printed on the pouch.

STORAGE AND STABILITY:

The test kit can be stored at temperatures between 4 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. Do not Freeze the kit.

SPECIMEN COLLECTION & PRESERVATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. To collect a nasopharyngeal swab specimen, insert a sterile swab into the nostril of the patient.
2. Using gentle rotation, push the swab until the resistance is met at the level of the turbinate..
3. Rotate the swab a few times against nasopharyngeal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. Do not use transport media, use the collected specimen and extraction buffer immediately. Be careful of contamination.
7. Specimen may be stored at R.T. for up to 1hours or at 2-8 ^{0} C for up to 4hours prior to testing.

Testing Procedure:

1. For in vitro diagnostic use only.
2. Carefully read IFU for using the COVID-19 Ag Test.
3. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
4. Withdraw the sterile swab from the nasal cavity.
5. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
7. Press the nozzle cap tightly the tube.
8. Apply 3 drops of extracted specimen to the specimen well of the test device.
9. Read the test result in 20-30 minutes.
10. Do not read result after 30 minutes.

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Does not use test kit beyond expiry date.
3. The test device should not be reused.
4. Do not freeze the Kits.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the test are done.
7. Clean up spills thoroughly using an appropriate disinfectant.

LIMITATIONS:

a. The test procedure, precaution and interpretation of results for this test must be followed strictly when testing.
b. The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimen.
c. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-COV-2 infection.

REFERENCES:

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
2. Diagnostic detection of Wuhan coronavirus 2019 by real time RT-PCR 2020.

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	Attention,see instructions for use		Consult Instructions For Use
IVD	For in vitro diagnostic use only	REF	Catalog #
4°C 30°C	Store between 4-30°C	2	Do not reuse
	Do not use if package is damaged	LOT	Lot Number
Σ	Tests per kit		Date of Manufacturing
	Manufacturer		Use by

IFU NO.: ABPL/IFU/075