Rapid Antigen Test for COVID19
ImCoV-Ag™

Reference Number: 70-1002
Pack Size: 25 Tests

Co-developed by IMGENEX India Pvt. Ltd. and ICMR-Regional Medical Research Centre, Bhubaneswar.

Lateral flow through chromatographic immunoassay for the qualitative detection antigen specific to SARS CoV-2 in human nasopharyngeal swabs.

INTRODUCTION

COVID-19 (Corona Virus Disease) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This new virus and disease were unknown before the outbreak began in Wuhan, China in December-2019. The virus is primarily spread between people during close contact, often via small droplets produced by coughing, sneezing, and talking. The droplets usually fall to the ground or onto surfaces rather than remaining in the air over long distances. People may also become infected by touching a contaminated surface and then touching their face. On surfaces, the amount of virus declines over time until it is insufficient to remain infectious, but it may be detected for hours or days. It is most contagious during the first three days after the onset of symptoms, although spread may be possible before symptoms appear and in later stages of the disease.

Symptoms: Common symptoms include fever, cough, fatigue, shortness of breath, and loss of smell and taste. While the majority of cases result in mild symptoms, some progress to viral pneumonia, multi-organ failure, or cytokine storm. The most estimates of the incubation period for covid-19 range from 1-14 days.

ASSAY PRINCIPLE

ImCoV-Ag™ COVID-19 Antigen Rapid test device has two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and Goat anti Mouse IgG antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 and Mouse IgG antibody conjugated with color particles are used as detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the specimen interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

INTENDED USE

ImCoV-Ag™ COVID-19 Antigen Rapid test device. lateral flow through immuno- chromatographic test for the qualitative detection of antigen specific to novel coronavirus (SARS- CoV-2) in human nasopharynx. It is intended to be used by healthcare professionals as an aid in the early diagnosis of infection with SARS-CoV-2 coronavirus.

CONTENTS OF KIT

ImCoV-Ag™ COVID-19 Antigen Rapid test device kit contains following items to perform the assay.

Kit Components	Quantity
Individually foil-pouched test devices with desiccant	25 Nos
Nasopharyngeal swab	25 Nos
Extraction buffer tube with nozzle	25 Nos
Extraction Buffer Bottle(4ml)	3 Nos
Instructions for use	1 No

Material required but not provided

- Medical mask and medical latex gloves
- Micro pipette and disposable pipette tips
- Watch or timer
- PPE Kit
- Biohazardous waste container

INTERPRETATION OF RESULTS

Line appear on test device window	Results
Only "C" line appear	**Negative**- No Coronavirus present in sample
Both "C" & "T" line appear	**Positive**- Coronavirus present in sample
No "C" line appear	**Invalid**- Repeat test with new device

LIMITATIONS

1. COVID-19 Antigen Rapid Test is designed for the primary test of SARS-CoV-2 antigen and only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

2. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.

3. Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.

4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

5. A negative test 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, Laboratory methods are recommended.

PERFORMANCE CHARACTERISTICS

Sensitivity & specificity: To establish the sensitivity and specificity of COVID-19 Antigen Rapid test kit was compared with pre-approved marketed device. This kit relative sensitivity and specificity in 50 samples. The aggregate is Sensitivity: 75% Specificity: 100%.

STORAGE & STABILITY

ImCoV-Ag™ COVID-19 Antigen Rapid test device kit should be stored at 2~30°C in driest place. The kit should not be frozen & must be protected from exposure to humidity and direct sunlight. It is sensitive to humidity and as well as to high temperature. Kit materials are stable until the expiration date printed on the outer box.

WARNING & PRECAUTIONS

- The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
- Use product insert to perform the assay.
- Do not use expired kit.
- Do not use the extraction buffer tube of another lot.
- Do not smoke, drink or eat while handling specimen.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
- The Test shall be performed by competent person only User are warned that this kit is intended only to be used by, and two supplement the Inform judgment of, appropriately quailed medical personal.
- All materials used in the assay and samples should be disposed off in accordance with established safety procedures.
- Spills should be decontaminated promptly with any other suitable disinfectant.
- Collected specimen should be prepared as sample in accordance with after-mentioned "Specimen Collection and Preservation" and tested as soon as possible
- When using samples from viral/universal transport media (VTM), it may cause inaccurate results due to decreasing the sensitivity of the test.
- When using swab for collecting specimen, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.
- Use Test device within 30 minutes after opening of aluminum pouch.

SPECIMEN COLLECTION & PRESERVATION

- Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way; place the swab specimen in the extraction tube with the extraction solution added in advance, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the swab antigen. *(See Instructional Diagram)*.
- Take extraction buffer bottle provided. Twist opens the cap and fill the extraction buffer 300-350 µl (10-12 drops) into the Extraction buffer tube.
- Insert the nasopharyngeal swab sample(s) into the extraction solution.
- Specimen should be tested as soon as possible after collection or can be stored at 2-8°C.

TEST PROCEDURE

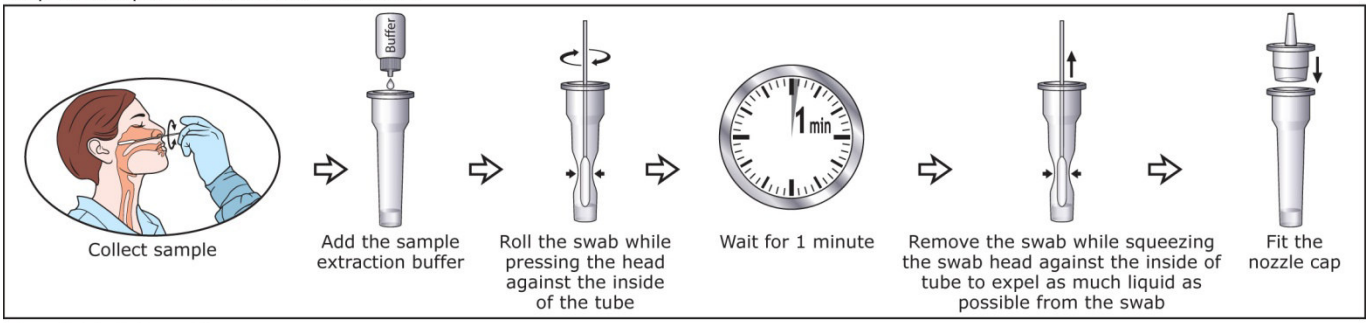
- Bring the ImCoV-Ag™ COVID-19 Antigen Rapid test kit components to room temperature at 15~30°C prior to testing.
- Open the device pouch, take out the test device from the aluminum pouch. Do not use test device if the desiccant color has changed from blue to pink. Label the test device with the test device with the patient identification number. Place the test device on a flat, clean and dry surface.
- Take the extraction buffer bottle provided, twist open the cap and fill the extract buffer tube up to the embossed marking or add 10-12 drops Approx. 300-350 µl of extraction buffer into extraction buffer tube. Collect the nasopharyngeal swab specimen with the help of nasopharyngeal swab provided inside the kit.
- Insert the swab specimen in the extraction buffer tube and swirl the swab 5 to 10 times. Wait for 1 minute.
- Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used Nasopharyngeal swab as biohazardous waste.
- Close the nozzle cap tightly onto the extraction buffer tube by pressing. Invert the extraction buffer tube vertically and gently squeeze it to dispense 2-3 drops of specimen into a specimen well on the device and wait for 15 to 20 minutes for result.

Notes:

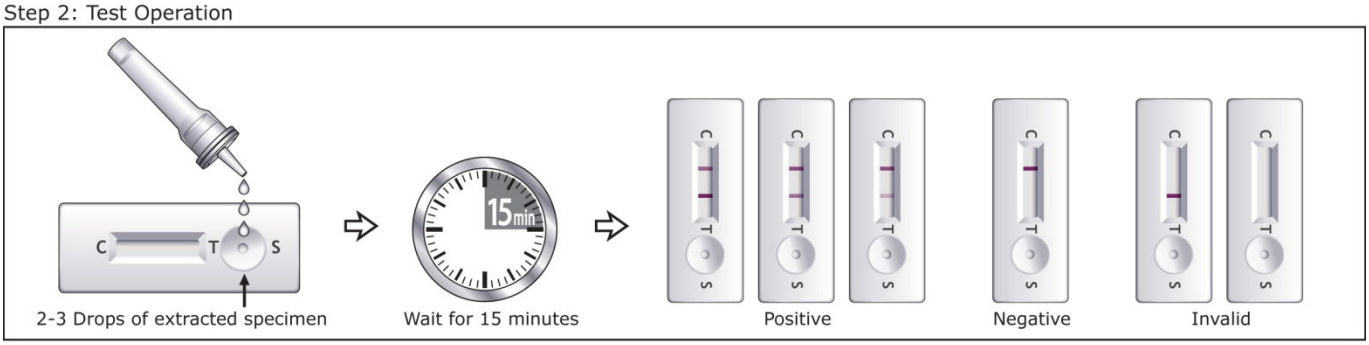
1. Add the exactly 2-3 drops of extraction buffer as there is a possibility of False Positive result when insufficient extraction buffer is used in the test and chances of over-flow, when more quantity of buffer will be used than specified limit.
2. Do not interpret after 20 minutes.
3. After recording the result, dispose of the test device and remaining extraction buffer tube solution as biohazardous waste.

Test Procedure Diagram

Step 1: Sample Collection and Extraction



Step 2: Test Operation



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3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol2016;24:490-502.
5. https://covid19.who.int

	Read instruction for use		Use by (Date of Expiry)	REF	Catalog Number
2°C 30°C	Store between 2°C-30°C		Manufactured by		Do not reuse
IVD	In-vitro Diagnostic use only		Date of Manufacturing		Protect from sunlight
LOT	Lot/Batch Number		Tests per Kit		Do not use if package is damage

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