INTENDED USE

Accucare® COVID-19 Ag Card test is used for in vitro qualitative detection of the antigen of novel Coronavirus in human throat swabs or nasal swabs.

For in vitro diagnostic use only.

ORDER INFORMATION

Pack Size	REF
25 Tests	CVGC 25
50 Tests	CVGC 50

SUMMARY AND EXPLANATION OF THE TEST

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST PRINCIPLE

This kit uses immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the specimen contains a novel coronaviruses antigen, the antibody will bind to the colloidal gold-labeled new coronavirus monoclonal antibody. The immune complex will be membrane fixed will be coronavirus monoclonal antibody capture, form the fuchsia line, display will be coronavirus antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

REAGENT AND MATERIAL

Reagents and Materials Provided

1) Antigen extraction tube (Pre-filled Antigen extraction buffer)
2) Test card
3) Sterile Nasal Swab
4) Instruction for use
5) Sample dropper

Material Required but Not Provided

1) Pipette Set; 2) Timer

WARNING AND PRECAUTION

1 This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

2 The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.

3 Do not open the sealed pouch unless ready to conduct the assay. Once opened, the cassettes should be used within 2 hours.

4 Do not use expired devices.

5 Bring all reagents to room temperature (15℃-30℃) before use.

6 Do not use the components in any other type of test kit as a substitute for the components in this kit.

7 Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

8 Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

9 Dispose of all specimens and materials used to perform the test as biohazardous waste.

10 Handle the Negative and Positive Control in the same manner as patient specimens.

11 The testing results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.

12 Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

13 The test methods and results must be interpreted in strict accordance with this specification.

14 Negative results will occur with this kit if the novel coronavirus antigen titer in the specimen falls below the minimum detection limit for this kit.

STORAGE AND STABILITY

1. Store the product at 2-30℃. The product is stable up to 24 months.
2. After the aluminum foil bag is unsealed, the test card should be used as soon as possible within one hour.

SPECIMEN COLLECTION AND PREPARATION

1. Throat swab:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little hard back and forth at least 3 times. ; 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 wall to release the antigen in the swab.

2. Nasal swab:

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.

3. Nasopharyngeal swabs:

Place the nasal swab into the sampling tube where the pharyngeal swab has been collected. In this way, there is a pharyngeal swab and a nasal swab in a sampling tube, so-called nasopharyngeal swab tube. Place the swab specimen in the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

TEST PROCEDURE

The test method was colloidal gold. Please read the manual and the instrument operation manual carefully before use.

1. Open the package and take out the test card and Extraction Tube contain Antigen extraction buffer.

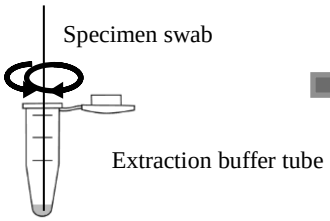
2. Take patient nasal swab, dip in the extraction tube and swirl 10-15 times in the extraction buffer ensuring the swab is immersed well in the extraction buffer.

3. Remove the swab from the extraction tube by pressing the swab gently onto the walls of the extraction tube. Mix well. Ensure the extracted sample is Mucous Free.

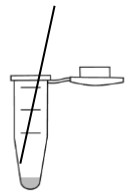
4. Add 2-3 full drops of mucous free of extracted antigen buffer mixture into the sample well of the test device, with the help of the dropper, and wait for 15 mins for the results to appear.

5. Discard the swab and extraction tubes and sample droppers properly as per biohazard disposal rules.

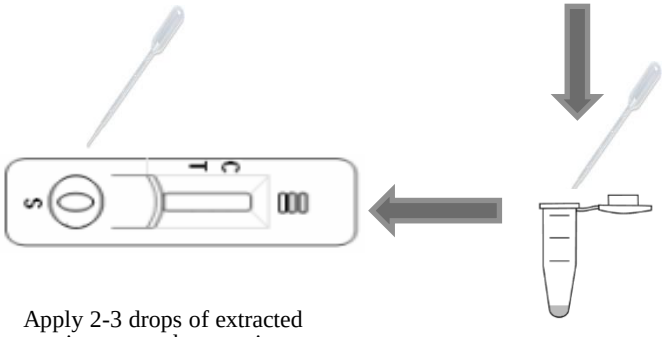
6. Read the results within 20 minutes. Strong positive results can be reported within 20 minutes, however, negative results must be reported after 20 minutes, and the results after 20 minutes are no longer valid.



Insert the swab into an extraction buffer tube. Stir the swab 10-15 times.



Remove the swab from the extraction tube by pressing the swab gently onto the walls of the extraction tube.



Apply 2-3 drops of extracted specimen to the specimen well of the test device, with the dropper.

Take the dropper and aspirate the extracted specimen into it.

15-20 mins

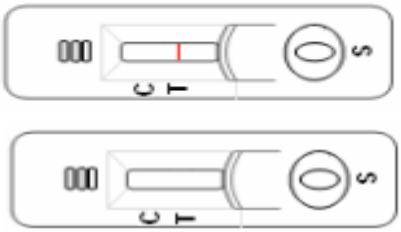
Read the test result in 15-20 minutes.

INTERPRETATION OF ASSSAY RESULT

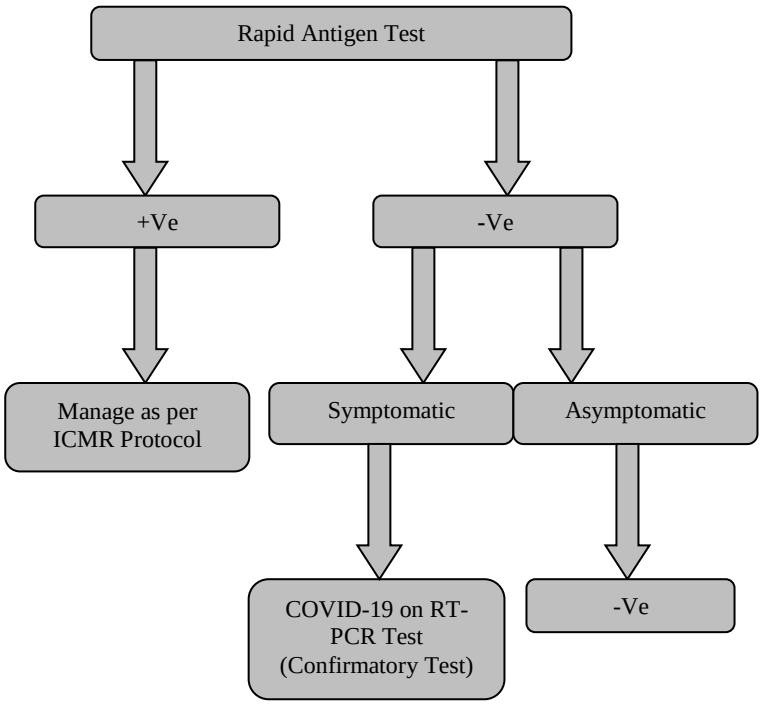
1 NEGATIVE RESULT: if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.

2 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.

3 INVALID: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be conducted again.



Strategy for Rapid Antigen based Test



LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

PERFORMANCE CHARACTERISTICS

Assay Cross Reactivity

However, there were no cross-reactivities of Human Adenovirus Respiratory syncytial virus, Human Rotavirus, Human Influenza Virus A and Human Influenza Virus B.

Interference

Not interfered for Whole blood, Mouth wash, Phenylephrine, Acetylsalicylic acid, Beclomethasone, Benzocaine, Flunisolide, Guaiacol glyceryl ether, Menthol, Oxymetazoline, Tobramycin, Zanamivir, Oseltamivir phosphate, mucous.

Clinical study

Under the strict IRB regulation, we collected total 175 patient's samples who were confirmed to be COVID-19 positive (25 samples) and it's negative (150 samples). The method of confirmation was RT-PCR.

N= 175		RT-PCR Test		Sum
		Positive	Negative	
Accucare COVID-19 Ag Test	Positive	21	0	21
	Negative	4	150	154
Sum		25	150	175

The overall diagnostic performance of the kit;

Sensitivity = 84.0%

Specificity = 100.0%

LIMITATION OF THE PROCEDURE

1 This reagent is only used for in vitro diagnosis.
2 This reagent is only used to detect human nasopharyngeal swab extracts. The results of other specimens may be wrong.
3 This reagent is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4 This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.
5 Failure to follow the test procedure and interpretation of test results may be adversely affect test performance and produce invalid result.
6 A negative 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.
7 A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of covid 19 infection and should be confirmed by viral culture or an molecular assay or ELISA.
8 Positive result, do not rule out co infections with other pathogen.
9 For more accuracy of immune status additional follow up testing using other laboratory method is recommended.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit
Σ	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry

ISO 13485:2016

CE

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 .Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com