

COVID-19 IgG / IgM Lateral Flow Assay Test Kit (Serum/Plasma/Whole Blood)

INTENDED USE

The Accucare Covid-19 IgG/IgM Cassette Rapid Test is a lateral flow immunoassay for qualitative detection of antibodies to 2019 novel coronavirus (SARS-CoV-2) in serum, plasma or whole blood specimens.

The Accucare COVID-19 IgG/IgM Cassette Rapid Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.

Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the qSARS-CoV-2 IgG/IgM Rapid Test early after infection is unknown.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long IgM or IgG antibodies may persist following infection. The Test must be confirmed with alternative testing method(s).

For prescription use only. For in vitro diagnostic use only. For emergency use authorization use only.

This rapid test is useful for epidemiological studies and surveillance purposes. This test has to be done under strict medical supervision.

ORDER INFORMATION

Pack Size	REF
1 Test	COVC 1
10 Tests	COVC 10
25 Tests	COVC 25
50 Tests	COVC 50

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from dromedary camels to humans. Several known coronaviruses are circulating in animals that have not infected humans yet.

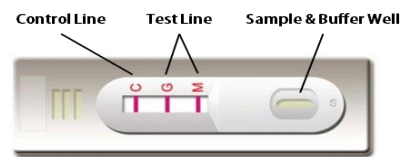
2019 Novel Coronavirus (SARS-CoV-2) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients reported with SARS-CoV-2 viral infections had mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. There is an urgent need for rapid tests to

manage the ongoing pandemic.

The Covid-19 IgG/IgM Rapid Test is intended for rapid and qualitative detection of antibodies indicative of SARS-CoV-2 infection and used as an aid for diagnosis of SARS-CoV-2 infection.

TEST PRINCIPLE

The Accucare Covid-19 IgG/IgM Cassette Rapid Test is a lateral flow chromatographic immunoassay which can detect antibodies against the SARS-CoV-2 virus. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and rabbit IgG-gold conjugates; 2) a nitrocellulose membrane strip containing an IgG line (G Line) coated with anti-human IgG, an IgM line (M Line) coated with anti-human IgM, and the C line (C Line) coated with goat anti-rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette. The anti-SARS-CoV-2 virus IgG, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti-human IgG line, forming a burgundy colored G line, indicating a SARS-CoV-2 virus IgG positive test result suggesting a secondary infection or previous infection.

IgM anti-SARS-CoV-2 virus, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the anti-human IgM line, forming a burgundy colored M line, indicating a SARS-CoV-2 virus IgM positive test result suggesting a fresh primary infection.

If both G line and M line are visible, the test result suggests late primary or early secondary SARS-CoV-2 infection. Absence of both test bands (G and M) suggests a negative result.

The test contains an internal control (C line) which should exhibit a burgundy colored band of goat anti-rabbit IgG/rabbit IgG-gold conjugate immunocomplex regardless of the color development on any of the test bands (G and M). Otherwise, the test result is invalid and the specimen must be retested again.

REAGENT AND MATERIAL

Reagents and Materials Provided

There are three kit sizes. Their kit component configurations are provided below:

		Kit Size (#of Test)		
		1	25	50
Components	Test Cassette (#)	1	25	50
	Sample Diluent (# of Bottle)	1	1	2
	Sample Dropper (#)	1	25	50
	IFU Leaflet	1	1	1

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Composition and Concentration

Conjugate pad Monoclonal Anti-SARS-CoV-2 antigen conjugated on the membrane

G line Anti human IgG

M line Anti human IgM

C line Goat anti rabbit IgG

Sample Buffer 0.01M PBS; PH 7.4

Material Required But Not Provided

1) Pipette Set; 2) Timer; 3) Specimen Collection Containers

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 Do not open the sealed pouch unless ready to conduct the assay. Once opened, the cassettes should be used within 2 hours.
- 3 Do not use expired devices.
- 4 Bring all reagents to room temperature (15°C-30°C) before use.
- 5 Do not use the components in any other type of test kit as a substitute for the components in this kit.
- 6 Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- 7 Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- 8 Dispose of all specimens and materials used to perform the test as biohazardous waste.
- 9 Handle the Negative and Positive Control in the same manner as patient specimens.
- 10 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.
- 11 Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

STORAGE AND STABILITY

1. Store the sample diluent at 2-30°C. The buffer is stable up to 24 months.
2. Store Accucare Covid-19 IgG/IgM Cassette Rapid Test at 2-30°C; shelf life is up to 24 months.
3. If stored at 2°C-8°C, ensure that the test device is brought to 15°C-30°C before opening.
4. Do not freeze the kit or store the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

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

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by venipuncture.
2. Separate the plasma by centrifugation.

3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by venipuncture.
2. Allow the blood to clot, and then separate the serum by centrifugation.
3. Carefully withdraw the serum into a new pre-labeled tube.
4. Test specimens as soon as possible after collecting. If specimens are not tested immediately store at 2°C-8°C for up to 5 days. The specimens should be frozen at -20°C for longer storage.

For frozen samples, avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Whole Blood

Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Do not use any hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

TEST PROCEDURE

Step 1: For fresh sample, begin with Step 2. For frozen samples, bring the specimens and test components to room temperature, mix the specimen well prior to assay once thawed.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Label the device with specimen ID number.

Step 4: Using a Sample Dropper, transfer one drop of serum, plasma or whole blood but not to exceed the more than one drop. The volume of the specimen is around 10µL of Serum / Plasma and 20µL of Whole Blood. For better precision, transfer specimen by a pipette capable of delivering 10µL/20µL of volume.

Holding the sample dropper vertically, dispense the one drop of specimen into the center of the sample well (S well) making sure that there are no air bubbles.

Then add 2 drops (about 70-100 µL) of Sample Diluent immediately into the sample well (S well).

Step 5: Set up a timer.

Step 6: Read the result in 15-20 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. If the C line does not develop, review the whole procedure and repeat test with a new device.
2. External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure

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the proper performance of the assay, particularly under the following circumstances:

- New operator uses the kit, prior to performing testing of specimens.
- A new lot of test kits is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit falls outside of 2-30°C.
- The temperature of the test area falls outside of 15 - 30°C.
- To verify a higher than expected frequency of positive or negative results.
- To investigate the cause of repeated invalid results.
- A new test environment is used (e.g., natural light vs. artificial light).

When performed properly, in addition to the presence of C band, no line should be visible for the negative control and the G or M or both lines are visible for the positive control. Additional controls may be qualified and tested by the user.

INTERPRETATION OF ASSAY RESULT

1 NEGATIVE RESULT: If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti-SARS-CoV-2 virus antibodies are detected. The result is negative or non-reactive.



2 POSITIVE RESULT:

In addition to the presence of C band, if only G band is developed, the test result indicates for the presence of IgG anti-SARS-CoV-2 virus; the result is IgG positive or reactive, suggesting late stage primary, early secondary or previous infection.



In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-SARS-CoV-2 virus. The result is IgM positive or reactive, suggesting fresh primary SARS-CoV-2 virus infection.



In addition to the presence of C band, both G and M bands are developed, the test indicates for the presence of IgG and IgM anti-SARS-CoV-2 virus. The result is IgG and IgM positive or reactive, suggesting current primary or early secondary SARS-CoV-2 virus infection.



Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

3 INVALID: If the C line is not developed, the assay is invalid regardless of color development of the T band as indicated below. Repeat the assay with a new device



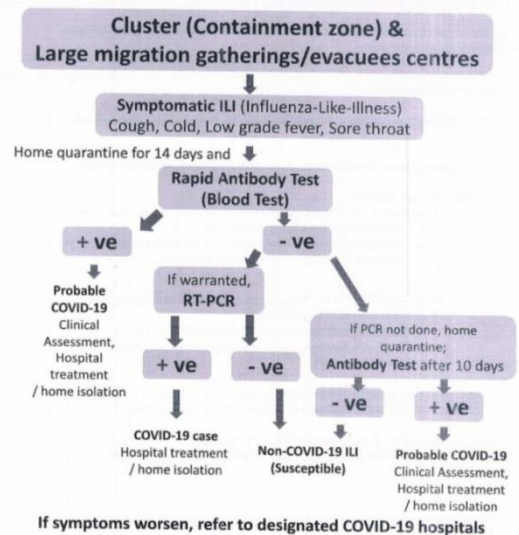
ICMR advisory notice for Antibody Test (4th April 2020)

Antibody Test Negative:

- If warranted, confirm by real-time RT-PCR using throat / nasal swab.
 - RT-PCR negative: Like non-COVID ILI(Influenza Like Illness)
 - RT-PCR positive: Confirmed COVID-19 case and action as per protocol to be initiated for isolation, treatment and contact tracing.
- If real-time RT-PCR not done home quarantine and repeat antibody testing after 10 days of the last rapid antibody test.
 - Antibody negative: Likely non-COVID-19 ILLNESS.
 - Antibody test positive: there is possibility of recent infection, quarantine for another 10days.

Antibody Test Positive: After Clinical Assessment, treatment in hospital or isolation as per protocol. Action as per protocol to be initiated for contract tracing.

STRATEGY FOR USE OF RAPID ANTIBODY BASED BLOOD TEST (4 April, 2020)



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Disclaimer

1. This antibody test is a supplementary tool to assess the prevalence of the diseases within a specific perimeter.
2. This antibody test will only be of utility after a minimum of 7 days of onset of symptoms.
3. The ICMR advisory for hot spots. Otherwise these test may used for :-
Any Hot spot may emerge in future.
or
As a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far.

PERFORMANCE CHARACTERISTICS

1 Clinical Performance

Testing of clinical specimens

180 negative serum or plasma samples collected prior to September 2019 were coded and tested together with the Covid-19 IgG/IgM Rapid Test. Of the 180 negative samples, one hundred seventy four (174) were tested negative.

Taken together, the Covid-19 IgG/IgM Rapid Test had a sensitivity and specificity of >90% and >95% respectively.

2 Assay Cross Reactivity

Serum or plasma sample containing antibodies reactive to one of following pathogens were tested along with unspiked samples in duplicate. No false positivity or false negativity was found:

- HBV,
- HCV,
- HIV-1&2,
- Syphilis
- Dengue Ag & Ab















LIMITATION OF THE PROCEDURE

- 1 The Assay procedure and sample interpretation must be the followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum or plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- 2 The Covid-19 IgG/IgM Cassette Rapid Test is limited to the qualitative detection of antibodies specific for SARS-CoV-2 virus. The intensity of the test line does not necessarily have linear correlation with virus titer in the specimen.
- 3 A negative or non-reactive result for an individual subject indicates absence of detectable antibodies for SARS-CoV-2 virus. However, a negative or non-reactive result does not preclude the possibility of SARS-CoV-2 virus infection.
- 4 A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limits of the assay, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.
- 5 If symptoms persist, while the result from the Covid-19 IgG/IgM Cassette Rapid Test is negative or non-reactive,

it is recommended to re-sample the patient a few days later or test with an alternative test device.

- 6 The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

GLOSSARY OF SYMBOL

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight		Content of the kit
	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry

Artwork No.: IFU/RC/COVC

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