# COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

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## INTENDED USE

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

## INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

## PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM) , anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilised on a nitrocellulose strip. The burgundy coloured conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM and/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG) the complex is trapped forming a burgundy coloured band which confirm a reactive test result. Absence of a coloured band in the test region indicates a non-reactive test result.

To serve as a procedural control, a coloured line will always change from blue to red in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS SUPPLIED

25 sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer
1 Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Lancets (for fingerstick whole blood only)
3. Centrifuge (for plasma only)
4. Timer
5. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

## SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venepuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

**Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.

**For Serum or Plasma Specimens:**

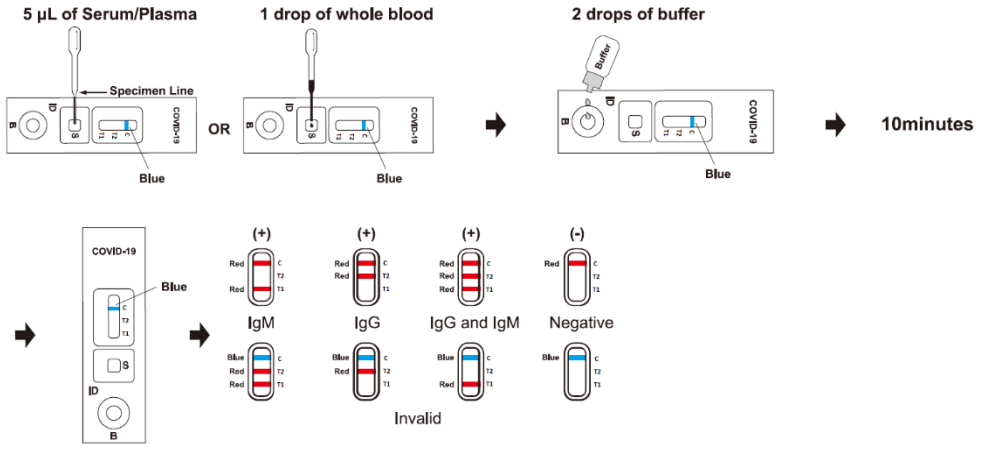
With a 5 µL mini plastic dropper provided, draw serum/plasma specimen to exceed the specimen line as showed in the following image and then transfer drawn serum/plasma specimen into the sample well ( S ). Then add 2 drops (about 80µL) of sample buffer to the buffer well ( B ) immediately. Avoid air bubbles.

**Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5 µL of volume.**

**For Whole Blood Specimen:**

Hold the 5 µL mini plastic dropper vertically and transfer 1 drop of whole blood (about 10µL) to the specimen well(S) of the test device, then add 2 drops (about 80µL) of sample buffer to the buffer well ( B ) immediately. Avoid air bubbles.

Wait for the coloured line(s) to appear. The result should be read in 10 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 15 minutes.



## INTERPRETATION OF RESULTS

**NEGATIVE:**
The coloured line in the control line region (C) changes from blue to red. No line appears in the test line regions T1 or T2. The result is negative.

**IgM POSITIVE:**
The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region T1. The result is anti-COVID-19 IgM positive.

**IgG POSITIVE:**
The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region T2. The result is anti-COVID-19 IgG positive.

**IgG and IgM POSITIVE:**
The coloured line in the control line region (C) changes from blue to red, and two coloured lines appear in test line regions T1 and T2. The result is anti-COVID-19 IgM and IgG positive.

**INVALID:**
Control line is still completely or partially blue, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test performance.

## LIMITATIONS

1. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background colour, making the interpretation of results difficult.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the anti-COVID-19 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE CHARACTERISTICS

Clinical Performance
The COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has been evaluated with the 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. The results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs etc.) of "Diagnosis and treatment of novel coronavirus pneumonia".
Regarding the IgM test, the result comparison to RT-PCR.

| Method | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| COVID-19 IgG/IgM Rapid Test | Positive | 87 | 0 | 87 |
| | Negative | 12 | 14 | 26 |
| Total | | 99 | 14 | 113 |

Regarding the IgG test, we have counted the positive rate of the 36 of 113 patients during the convalescence period.

| Method | | Number of patients during the convalescence period | Total |
|---|---|---|---|
| COVID-19 IgG/IgM Rapid Test | Positive | 35 | 35 |
| | Negative | 1 | 1 |
| Total | | 36 | 36 |

The sensitivity of IgM test is 87.9% (87/99) and specificity is 100%(14/14) comparison to RT-PCR.
The sensitivity of IgG test is 97.2% 35/36 during the convalescence period, and specificity is 100% 14/14 .

## REFERENCES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3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.


## INDEX OF SYMBOLS

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|---|---|---|---|---|---|
| | Consult instructions for use | Σ | Tests per kit | EC REP | Authorised representative |
| IVD | For in vitro disgnostic use only | | Use by | | Do not reuse |
| 2°C 30°C | Store between 2 ~30°C | LOT | Lot number | REF | Catalogue # |

REF COVID-TEST


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