COVID-19 IgG/IgM Rapid Test Kit
(Whole Blood/Serum/Plasma)
For Professional Use

INTENDED USE

COVID-19 IgG/IgM Rapid Test Kit (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 Coronavirusi 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 kit (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.4 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 kit (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 colored 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 &/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 &/or anit-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

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

MATERIALS SUPPLIED

If whole blood test, sealed pouches each containing a test kit, a ***4 μ***L mini plastic dropper and a desiccant
1 Buffer
1 package insert
If serum/plasma test,sealed pouches each containing a test kit and a desiccant
1 Buffer
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Lancets (for fingerstick whole blood only)
2. Centrifuge and Pipette (for plasma/serum only)
3. Timer

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 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, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test kit (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 hemolysis. Use only clear, non-hemolyzed 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 venipuncture 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

For Serum or Plasma Specimen**s:**

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

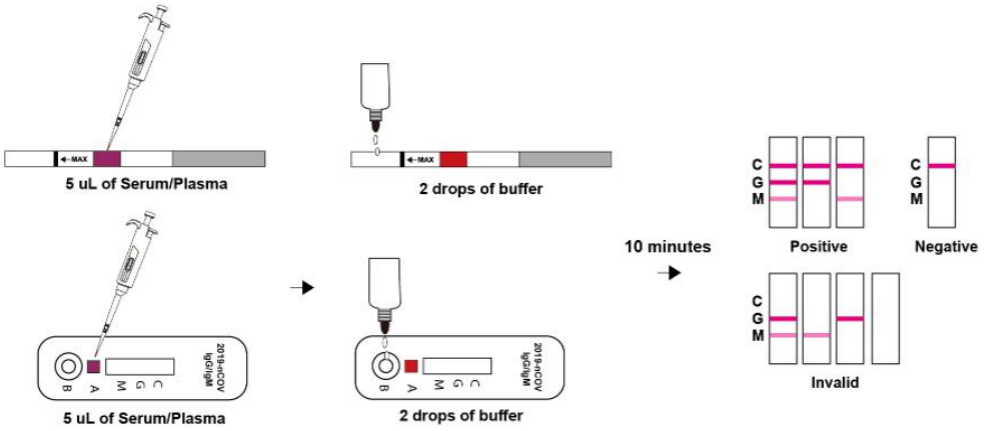
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test kit on a clean and level surface.

Strip:Add 5***uL*** of serum/plasma to the sample pad(purple place with Colloidal gold) of the test strip,then add 2 drops (about 60 μL) of sample buffer to the buffer pad (top of the strip) immediately.

Cassette:
Add 5***uL*** of serum/plasma to the specimen well(A) of the test cassette, then add 2 drops (about 60 μL) of sample buffer to the buffer well (B) immediately.

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



For Whole Blood Specimen

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

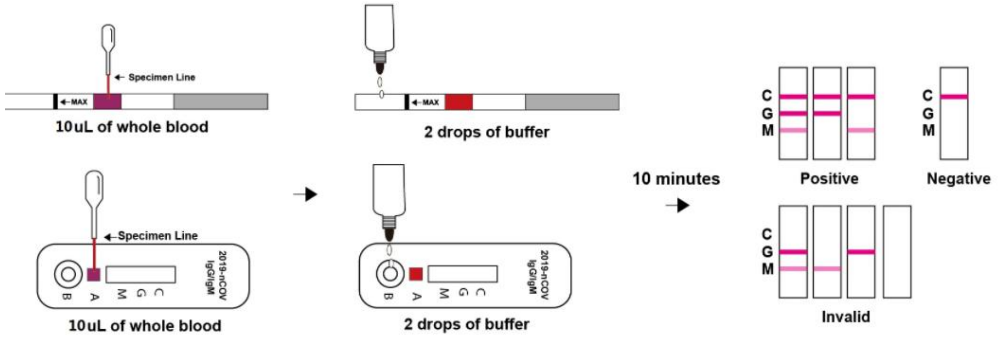
1. Remove the test strip/cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test device on a clean and level surface.

Strip:Add ***10uL*** of whole blood to the sample pad(purple place with Colloidal gold) of the test strip,then add 2 drops (about 60 μL) of sample buffer to the buffer pad (top of the strip) immediately.

Cassette:
Add ***10u***L of whole blood to the specimen well(A) of the test cassette, then add 2 drops (about 60 μL) of sample buffer to the buffer well (B) immediately.

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



INTERPRETATION OF RESULTS

NEGATIVE: If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates that no anti-COVID-19 antibodies are detected in the specimen. The result is negative.

IgM POSITIVE:

In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID-19 in the specimen. The result is IgM anti-COVID-19 positive.

IgG POSITIVE:

In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-COVID-19 in the specimen. The result is IgG anti-COVID-19 positive.

IgG and IgM POSITIVE:

In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti-COVID-19 positive.

INVALID:

Control line fails to appear. 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 kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 color, 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.

REFERRENCE

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2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
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.