REF 600092 CE 25TEST

COVID-19 IgG/IgM Rapid Test Kit (WB/Serum/Plasma)

INTENDED USE

The COVID-19 IgG/IgM Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV, a new strain of coronavirus (nCoV), in whole blood, serum and plasma specimen.

SUMMARY

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 antimouse 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 mouse 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 immuno-complex goat anti mouse IgG/mouse 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

Individually pouched test devices with droppers
Buffer
Instructions for Use sheet

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, specimen collection container, centrifuge

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 expirationdate.

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, nonhemolyzed 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

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

For Serum and Plasma samples

Using the dropper take in sample up to the fill line (approximately 10 μl) and transfer it to the sample well. Add 2 drops of buffer to the sample well (approximately 80 μl) and start the timer. See illustration below. Using a pipette, transfer 10 μl of serum or plasma to the sample well, add 2 drops of buffer (approximately 80 μl) and start the timer.

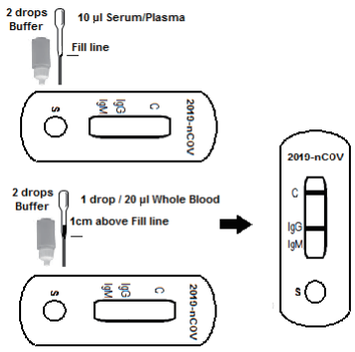
For Venepuncture Whole Blood

Using the dropper take in whole blood to approximately 1 cm above the fill line then expel 1 full drop (approximately 20 μl) into the sample well. Add 2 drops of buffer to the sample well (approximately 80 μl) and start the timer.
Using a pipette, transfer 20 μl of whole blood to the sample well, add 2 drops of buffer (approximately 80 μl) and start the timer.

For Finger Prick Whole Blood

Using the dropper take in whole blood to approximately 1 cm above the fill line then expel 1 full drop (approximately 20 μl) into the sample well. Add 2 drops of buffer to the sample well (approximately 80 μl) and start the timer.

Using a capillary tube, fill the tube with blood by capillary action from the puncture site and expel approximately 20 μl into the sample well. Add 2 drops of buffer to the sample well (approximately 80 μl) and start the timer.



Wait for coloured lines to appear. Read the results at 10 minutes. Positive result may be visible as soon as 2 minutes. Do not interpret any 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:

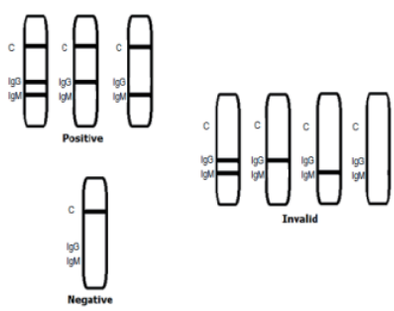
In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID-19 in the specimen. The result is IgM anti-COVID-19 positive.

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.

PERFORMANCE CHARACTERCS

1. Clinical Performance for IgM Test

The samples from susceptible subjects were tested by The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and by a commercial IgM EIA kit. Relative Sensitivity: 95.7%, Relative Specificity: 97.3%, Overall Agreement: 96.8%

2. Clinical Performance for IgG Test

The samples from susceptible subjects were tested by the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and by a commercial IgG EIA kit. Relative Sensitivity: 91.8%, Relative Specificity: 96.4%, Overall Agreement: 95.0%

REFERRENCE

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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.

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