COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow immunoassay designed for the qualitative detection of IgG and IgM antibodies to the SARS-CoV-2 virus in whole blood, serum or plasma specimens from individuals suspected of COVID-19 infection by their healthcare provider.

The COVID-19 IgG/IgM 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. It is suggested to use as a supplementary test indicator for suspected cases with negative nucleic acid test of novel coronavirus or used in conjunction with nucleic acid test in suspected cases. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains.

The test is intended to be used at clinical laboratories or by healthcare workers at the point-of-care, not for home use. The test should not be used for screening of donated blood.

[SUMMARY]

Coronavirus disease 2019 (COVID-19) is caused by a coronavirus. Coronaviruses are a large family of viruses which may cause illness in animals or humans. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (named SARS-CoV-2).

The virus that causes COVID-19 is mainly transmitted through droplets generated when an infected person coughs, sneezes, or speaks. It is currently thought that an infected person can go up to 14 days before noticing any symptoms. According to WHO, the incubation period is, on average, five to six days. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. There have been reports of persons who were infected by individuals who had only shown slight or non-specific symptoms of disease. In some patients, the virus can lead to severe illness, including difficult breathing, and to pneumonia. Deaths have mainly occurred among patients who were elderly and/or had prior underlying chronic illnesses.

When the SARS-CoV-2 virus infects an organism, RNA, the genetic material of the virus, is the first marker that can be detected. The viral load profile of SARS-CoV-2 is similar to that of influenze, which peaks at around the time of symptom onset, and then begin to decline. With the development of the disease course after infection, the human immune system will produce antibodies, among which IgM is the early antibody produced by the body after infection, indicating the acute phase of infection. 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. IgG indicates the convalescent phase of infection or a history of past infection. However, both IgM and IgG have a window period from virus infection to antibody production, IgM almost appear after the onset of disease several days, so their detection often lags behind nucleic acid detection and is less sensitive than nucleic acid detection. In cases where nucleic acid amplification tests are negative and there is a strong epidemiological link to COVID-19 infection, paired serum samples (in the acute and convalescent phase) could support diagnosis.

[PRINCIPLE]

The COVID-19 IgG/IgM Rapid Test Cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloid gold (SARS-CoV-2 conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with the Mouse anti-Human IgM antibody, IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgM antibodies to SARS-CoV-2, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a anti-SARS-CoV-2 IgM positive test result. IgG antibodies to SARS-CoV-2 if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a anti-SARS-CoV-2 IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with Mouse anti-Human IgM antibody and Mouse anti-Human IgG antibody on the test line, and a dye pad which contains colloidal gold coupled with SARS-CoV-2 virus recombinant antigen.

The quantity of tests was printed on the labeling.

Materials Provided

- Test cassette
- Dropper
- Buffer(PBS, ProClin300)
- Package insert

Materials Required But Not Provided

- Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at the temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

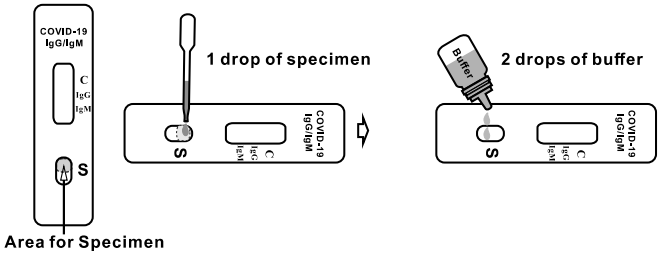
[SPECIMEN]

- The test can be used to test whole blood (venipuncture blood and capillary finger prick blood) /serum /plasma (EDTA, heparin, citrate) specimens.
- To collect whole blood, serum or plasma specimens following regular clinical laboratory procedures.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store serum/ plasma/ anticoagulated venipuncture whole blood specimens at 2-8℃ for up to 3 days. The serum/plasma specimens should be frozen at -20℃ (-4℉) for longer storage. Do not freeze whole blood specimens.
- Fresh fingerstick blood specimens should be collected and tested immediately.
- 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.

[TEST PROCEDURE]

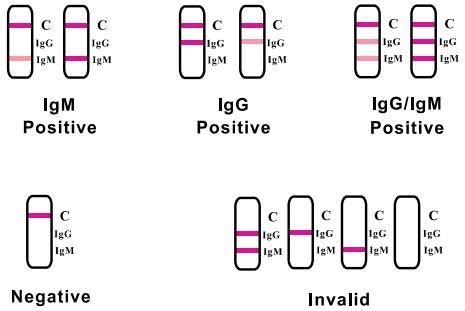
Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop (approximately 10μl) of specimen into the front of the specimen well (S) making sure that there are no air bubbles. For better precision, transfer specimen by a pipette capable of delivering 10μl of volume. See the illustration below.
3. Then, add 2 drops (approximately 70μl) of buffer immediately into the specimen well (S).
4. Start the timer.
5. Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]



Positive: Control line and at least one test line appear on the membrane. The appearance of IgG test line indicates the presence of IgG antibodies to SARS-CoV-2 virus. The appearance of IgM test line indicates the presence of IgM antibodies to SARS-CoV-2 virus. And if both IgG and IgM line appear, it indicates that the presence of both IgG and IgM antibodies to SARS-CoV-2 virus. Regardless of how dark or light the line may appear.

Negative: One colored line appears in the control region (C). No apparent

colored line appears in the test line region.
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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

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

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The COVID-19 IgG/IgM Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antibody in the blood.
- Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
- If symptoms persist and the result from the COVID-19 IgG/IgM Rapid Test Cassette is negative, it is recommended to re-sample the patient a few days later or test with an alternative test device.
- A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.
- Proper sample collection is critical, and failure to follow the procedure may give inaccurate results. Improper sample collection, improper sample storage or repeated freezing and thawing of samples can lead to inaccurate results.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Summary data of COVID-19 IgG/IgM Rapid Test as below:
Regarding the IgM test, testing was performed on 167 clinical specimens from individuals suspected of COVID-19 infection compared to RT-PCR.
COVID-19 IgM:

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

A statistical comparison was made between the results yielding a sensitivity of 87.01%, a specificity of 98.89% and an accuracy of 93.41%.

Regarding the IgG test, we have counted the positive rate of the 77 patients during the convalescence period.

COVID-19 IgG:

COVID-19 IgG		Number of patients during the convalescence period	Total
CLUNGENE®	Positive	75	75
	Negative	2	2
Total		77	77

The results yielding a sensitivity of 97.40%.

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross reactivity with the test. Some positive specimens of other common infectious diseases were spiked into the Novel coronavirus positive and negative specimens and tested separately. No cross reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, TP, HTLV, CMV, FLUA, FLUB, RSV, MP, CP, HPIVs.

2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Novel coronavirus positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	20μg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200μg/ml	+	-
Lipids	20mg/ml	+	-

3. Some other common biological analytes were spiked into the Novel coronavirus positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc. (μg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

Reproducibility

Reproducibility studies were performed for Novel coronavirus IgG/IgM Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100 %.

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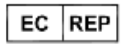
Index of Symbol


Do not reuse


Store between 4-30℃



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