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

LUMIRATEK

Package Insert

REF INGM-MC42 English

A rapid test for the qualitative detection of antibodies (IgG and IgM) to SARS-CoV-2 in whole blood, serum, or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of SARS-COV-2 infections.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma.

【PRINCIPLE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

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

【SPECIMEN COLLECTION AND PREPARATION】

- The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- Whole blood or plasma could be collected with tube containing Heparin or Citrate.
- To collect Fingerstick Whole Blood Specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper, capillary or micropipette measuring 10ul. The dropper provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the dropper or capillary.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS 】

Materials provided

Test cassettes
Droppers or capillaries
Buffer
Package insert

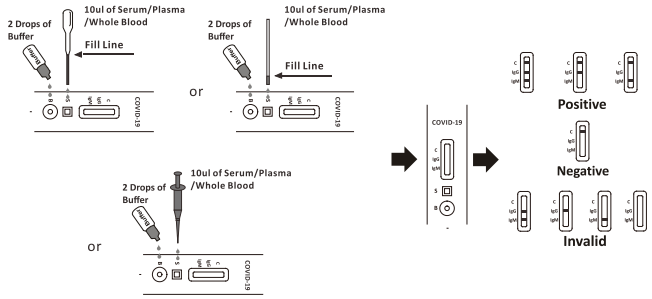
Materials required but not provided

Specimen collection containers
Centrifuge (for plasma only)
Micropipette
Timer
Lancets (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - For Serum or Plasma or Whole Blood Specimens:
     - To use a dropper/ capillary: Hold the dropper/ capillary vertically, draw the specimen up to the Fill Line (approximately 10μl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
     - To use a micropipette: Pipette and dispense 10μl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80μl) to the buffer well (B) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

IgG and IgM POSITIVE:* **Three lines appear**. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

IgG POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.

IgM POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s).

INVALID: **Control line fails to appear**. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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 procedure and to verify proper test performance.

【LIMITATIONS】

1. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
2. In the early onset of symptom，anti-SARS-COV-2 IgM concentrations may be below detectable levels.
3. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
4. Results from immunosuppressed patients should be interpreted with caution.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
6. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
7. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
8. 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.
9. Not for the screening of donated blood.
10. There may be false positive risk with the plasma in EDTA tube after a period storage.

【PERFORMANCE CHARACTERISTICS】

POSITIVE AGREEMENT

Positive agreement of the COVID-19 IgG/IgM rapid test was evaluated using clinical samples collected from symptomatic subjects. All subjects were confirmed positive for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

NEGATIVE AGREEMENT

Negative agreement of the COVID-19 IgG/IgM rapid test was evaluated using clinical samples collected from symptomatic subjects. Samples were collected during the COVID-19 pandemic and all were excluded for COVID-19 by Nucleic Acid Test (RT-PCR) or clinical diagnosis.

The positive and/or negative population consisted of the following subjects.

- Living in site A during the COVID-19 pandemic.
- Living in site B during the COVID-19 pandemic.
- Living in site C during the COVID-19 pandemic.

Site A	PCR Positive (Confirmed Cases)				PCR Negative (Excluded Cases)
Course of Disease	Early Period	Medium Period	Later Period	Convalescent	N/A
Days Between Symptom Onset and Blood Collection	<or =7days	8-14days	15-21days	>or= 22days	
IgG+ and IgM+	0	57	10	17	1
IgM+ and IgG-	1	4	1	3	3
IgM- and IgG+	1	1	0	0	0
IgM- and IgG-	0	3	1	1	146
Total	2	65	12	21	150
Agreement	2/2=100%(95%CI:22.4%~100.0%)	62/65=95.4%(95%CI:87.1%~99.0%)	11/12=91.7%(95%CI:61.5%~99.8%)	20/21=95.2%(95%CI:76.2%~99.9%)	146/150=97.3%(95%CI:93.3%-99.3%)

CI means confidence interval.

Site B	Confirmed Cases			PCR Negative (Excluded Cases)
Course of Disease	Early Period	Medium Period	Later Period	N/A
Days Between Symptom Onset and Blood Collection	<or =7days	8-14days	>or= 15days	
IgG+ and IgM+	1	26	33	0
IgM+ and IgG-	0	10	3	0
IgM- and IgG+	0	1	2	0
IgM- and IgG-	31	5	1	50
Total	32	42	39	50
Agreement	1/32=3.1%(95%CI:0.08%-16.2%)	37/42=88.1%(95%CI:74.3%-96.0%)	38/39=97.44 %(95%CI:86.5%~99.9%)	50/50=100% (95%CI:94.2%~100.0%)

CI means confidence interval

Site C	Confirmed Cases	Excluded Cases
Days Between Symptom Onset and Blood Collection	Unknown	N/A
IgG+ and IgM+	58	0
IgM+ and IgG-	5	0
IgM- and IgG+	1	0
IgM- and IgG-	6	10
Total	70	10
Agreement	64/70=91.4% (95%CI:82.3%-96.8%)	10/10=100.0% (95%CI:74.1%-100.0%)

CI means confidence interval

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, anti-haemophilus influenza, ANA, H1N1, H3N2, H7N9, coronavirus HKU1, NL63, OC43, 229E and HAMA positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor. It is possible to cross-react with samples positive for MERS-CoV antibody.

Interfering Substances

The following potentially interfering substances were added to COVID-19 negative and spiked positive specimens.

Analytes	Concentration	Result			
		Negative Specimen		Spiked with Positive Specimen	
		IgG line	IgM line	IgG line	IgM line
Acetaminophen	20 mg/dL	Negative	Negative	Positive	Positive
Caffeine	20 mg/dL	Negative	Negative	Positive	Positive
Albumin	2 g/dL	Negative	Negative	Positive	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Gentisic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Ethanol	1%	Negative	Negative	Positive	Positive
Ascorbic Acid	2g/dL	Negative	Negative	Positive	Positive
Creatine	200mg/dl	Negative	Negative	Positive	Positive
Bilirubin	1g/dL	Negative	Negative	Positive	Positive

Hemoglobin	1000mg/dl	Negative	Negative	Positive	Positive
Oxalic Acid	60mg/dL	Negative	Negative	Positive	Positive
Uric acid	20mg/ml	Negative	Negative	Positive	Positive

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

Manufacturer BiotesT
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Number: RP5326010
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