COVID-19 IgM/IgG Rapid Test

(Whole Blood / Serum / Plasma)

For In Vitro Diagnostic Use Only

For Professional Use Only

INTENDED USE

The COVID-19 IgM/IgG Rapid Test is a lateral flow immunoassay test device for the rapid presumptive qualitative simultaneous detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma.

SUMMARY

Coronavirus (CoV) belongs to the Coronaviridae family. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route as well. There are seven known types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 was first reported in 2019 in Wuhan, China with viral pneumonia cases and clinical manifestations of fever, fatigue, cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. The disease caused by SARS-CoV-2 infection in humans is formally known as COVID-19. COVID-19 can develop into a serious illness requiring hospitalization and even leading to patient death.

PRINCIPLE

The COVID-19 IgM/IgG Rapid Test is a lateral flow immunoassay qualitative rapid test that employs a unique combination of SARS-CoV-2 antigen-coated colored particles (colloidal gold dye particles) for the rapid presumptive qualitative simultaneous detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma. In the IgG component of the COVID-19 IgM/IgG Rapid Test, 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 by capillary action and reacts with the anti-human IgG in the 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 of the COVID-19 IgM/IgG Rapid Test, anti-human IgM is coated in the IgM test line region. During testing, the specimen reacts with anti-human IgM. SARS-CoV-2 IgM antibodies, if present in the specimen, react 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 SARS-CoV-2 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains SARS-CoV-2 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain SARS-CoV-2 antibodies, 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.

CONTENTS OF KIT

PART NUMBER: CV19-CK25 / KIT CONTENTS (25 TESTS PER KIT)

COVID-19 IgM/IgG Test Cassette (PART# CV19-CK)	25 Cassettes (Individually sealed in pouch with 1-gram desiccant)
COVID-19 Test Buffer (PART# CV19-B)	1 Bottle (5mL)
Plastic Pipette (dropper)(20µL)	25 Pipettes
Product Insert	1 Copy

MATERIALS REQUIRED BUT NOT PROVIDED

1.Personal protective equipment such as gloves, lab coat or gown.
2. Appropriate biohazard waste containers.
3. Absorbent cotton for fingerstick or venipuncture wound closure.
4.Alcohol Swab
5. Fingerstick Lancet
6. Timer.

FOR VENIPUNCTURE BLOOD COLLECTION AND PLASMA SPECIMENS:
1. Venipuncture apparatus if collecting blood specimens.
2. Appropriate blood collection tubes.
3. Precision pipette capable of delivering 10-50µl of specimen.
4. Appropriate shipping containers.
5. Personal protective equipment.
6. Appropriate biohazard waste containers and disinfectants.
7. Centrifuge to process a plasma specimen.

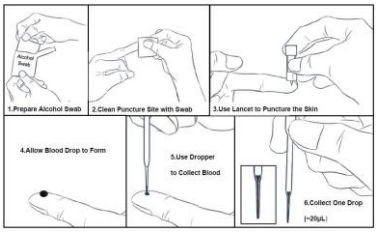
STORAGE AND STABILITY

- The COVID-19 IgM/IgG Rapid Test Kit contents are stable prior to the expiration date printed on test cassette foil pouch. The test cassette is to be stored at 4℃~30℃ and should be kept dry and away from direct sunlight.
-Refer to the package for the production date and expiry date Do not freeze and not use beyond the expiration date.
- This reagent is to be used within 1 hour once the foil pouch is unsealed. If the temperature is higher than 30℃ or in a high humidity environment. This reagent should be used immediately after opening.

MATERIALS REQUIRED BUT NOT PROVIDED

Proper specimen collection and handling is critical to the performance of this test. Specimens should be tested as soon as possible after specimen collection. **For Fingerstick Whole Blood:** Following laboratory procedures, clean the finger of the person being tested with an alcohol swab. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Use a lancet to puncture the skin just slightly off the center of the finger and allow blood drop to form. Use 20µL dropper provided to collect fingerstick whole blood sample.

TABLE 1. FINGERSTICK WHOLE BLOOD PROCEDURE



For Venous Whole Blood: Draw blood following laboratory procedure for obtaining venous blood. Depending on use, collect sample in a tube containing heparin or EDTA. Be sure the tube of blood is well mixed before sampling. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).
For Plasma: Collect plasma in a tube containing EDTA following standard laboratory procedures. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).

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TEST PROCEDURE

SAMPLE PREPERATION

1. Prior to beginning the test, ensure that all clinical specimens and test materials are at room temperature.
2. Check the expiration on each individual reagent and outer kit box before using the test. Do not use any tests past the expiration date on the label.
3. Use Universal Biological Precautions when handling any clinical specimen.

WHOLE BLOOD (VENIPUNCTURE/FINGERSTICK) SPECIMEN

- To use a dropper: Hold the dropper vertically, draw the specimen into the dropper and transfer 1 drop of whole blood (approximately 20µL) to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.
- To use a micropipette: Pipette and dispense 20µL of whole blood to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.

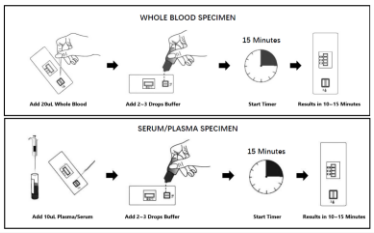
SERUM OR PLASMA SPECIMEN

-To use a dropper: Hold the dropper vertically, draw the specimen up into the dropper and transfer one small drop (approximately 10µL) of the specimen to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer. Avoid trapping air bubbles in the SAMPLE WELL.

-To use a micropipette: Pipette and dispense 10µL of serum or plasma to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.

TEST WORKFLOW

TABLE 2. TEST PROCEDURE



INTERPRETATION OF RESULTS

READ TIME: Read the results at 10 to 15 minutes, do not interpret the results after 15 minutes.
LINE VISIBILITY: Any visible line, regardless of how strong or weak the color signal, IS A LINE.
NEGATIVE: Test is **NEGATIVE** for COVID-19 if: Only control line (C) is visible.
A negative result is a presumptive negative. Negative result does not exclude possible infection with SARS-CoV-2 virus. As with any test, providers must consider the patient's likelihood of exposure and the possibility of false laboratory results when making treatment or other patient management decisions. Professional Health Care Providers should follow all relevant CDC guidance, as well as local and state regulations to determine the appropriate course of action for result confirmation and prescribed treatment.

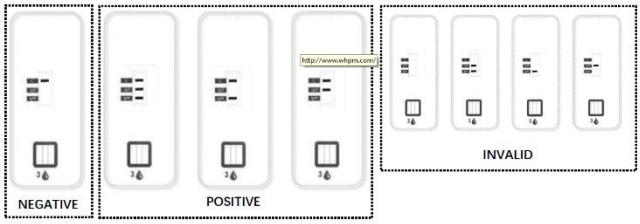
WARNING: Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

POSITIVE: Test is **POSITIVE** for COVID-19 if:
A. Control line (C), IgM (Line 1), and IgG (Line 2), are visible.
B. Control line (C) and IgM (Line 1) are visible.
C. Control line (C) and IgG (Line 2) are visible.
A Positive result is a presumptive positive. Healthcare providers who have obtained a presumptive positive patient for COVID-19 should contact their local or national health department immediately for consultation and guidance.

WARNING: 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.

INVALID: Test is **INVALID** if: Control line (C) is **NOT VISIBLE** regardless of the IgM (Line 1), and IgG (Line 2) result.
An INVALID test result indicated that there may be a problem with the testing procedure of the COVID-19 IgM/IgG Rapid Test. In the event of an INVALID result it is recommended that the Health Care Provider conduct the test again using a new COVID-19 IgM/IgG Rapid Test cassette. If issues persist, please contact MYM Supply Laboratory.

TABLE 2. RESULT INTERPRETATION



WARNING: 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.
WARNING: THIS TEST HAS NOT BEEN REVIEWED BY FDA.

WARNINGS AND PRECAUTIONS

-For In Vitro Diagnostic Use Only.
-Local and national public health agencies should be notified of any patient suspected to have COVID-19. -Confirmatory testing is necessary for positive detection results and may be necessary for negative detection results. Laboratories should consult with local or national public health officials on any positive detection OR no detection (negative) COVID-19 test result on the need for additional testing and appropriate transportation of specimens.
-Use of this assay should be limited to designated, trained personnel.
-All personnel who are involved in collecting, processing, handling, or transporting specimens from a patient with suspected COVID-19 should take appropriate precautions following the procedures recommended by local or national public health officials.
-Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.
-Dispose of all specimens and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a sealed, puncture-resistant container prior to disposal.
-Do not use any device if the pouch has been perforated.
-Each device is for single use only.
-Always check expiration date prior to testing. Do not use the test beyond the expiration date printed on the pouch.
-If desiccant packet is missing, do not use, discard and use a new test device.
-Adequate lighting is required to read the test results.

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QUALITY CONTROL

Each COVID-19 IgM/IgG Rapid Test Kit contains a built-in procedural control feature. When running the test, the appearance of a red Control Line **(C)** in each test indicates proper functioning of the buffer reagents, capillary flow, and functional integrity of the test strip within the cassette. If the Control Line does not appear, the test is considered Invalid.

Controls included in the Kit: Internal positive control **(C)** (built into each test cassette)

PERFORMANCE CHARACTERISTICS

SENSITIVITY, SPECIFICITY AND ACCURACY

Comparison results of the clinical application performance of the COVID-19 IgM/IgG Rapid Test was confirmed with specimens collected from healthy individuals as well as from confirmed COVID-19 patient specimens.

TABLE 3. CLINICAL APPLICATION PERFORMANCE

COVID-19 IgM/IgG Rapid Test		Confirmed COVID-19 Patient Serum		
		Positive	Negative	Total
IgM/IgG	Positive	43	0	43
	Negative	3	0	3
Total		46	0	46

(1) The specimens of 100 healthy individuals were collected and tested. The test results of the COVID-19 IgM/IgG Rapid Test were all negative. The IgM/IgG antibody negative coincidence rate was 100%. Demonstrating a clinical specificity of 100%.
(2) The specimens of 46 clinically confirmed COVID-19 patients with an infection timeline of 4-24 days were tested. The IgM/IgG antibody combined positive coincidence rate was 43/46, demonstrating a clinical sensitivity of 93.5%.
(3) A total of 146 specimens were tested. The comparison results of the clinical application performance of the COVID-19 IgM/IgG Rapid Test with the expected results of the known negative and confirmed positive specimens was 143/146, demonstrating a relative accuracy of 97.3%.

TABLE 4: CLINICAL SENSITIVITY, SPECIFICITY, AND RELATIVE ACCURACY

COVID-19 IgM/IgG Rapid Test	
Sensitivity	93.5%
Specificity	100%
Relative Accuracy	97.9%

CROSS-REACTIVITY

Controlled studies of potentially cross-reactive substances were performed on negative samples using the COVID-19 IgM/IgG Rapid Test. The COVID-19 IgM/IgG Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for H1N1, H3N2, H5N1, H7N9, influenza B virus, RSV (respiratory syncytial virus), Human rhinovirus 2, adenovirus 5, adenovirus 7, measles virus, cytomegalovirus, rotavirus, mumps virus, herpes zoster virus, mycoplasma, pneumoniae; The results showed no cross-reactivity.

INTERFERING SUBSTANCES

The following compounds have been tested using the COVID-19 IgM/IgG Rapid Test Cassette and no interference was observed. Mucin:14mg/g/ Bilirubin:200mg/L/ Cholesterol:2500mg/L/ Triglyceride: 2500mg/L / Hemoglobin:25g/L / Human Haemoglobin:30mg/g / Human Blood:200μL/g/ Interferon-alpha:2mg/g / Zanamivir:2mg/g / Ribavirin:2mg/g / Oseltamivir:2mg/g / Peramivir:2mg/g /Lopinavir:2mg/g / Ritonvir:2mg/g / Arbidol:2mg/g.

INTERPRETATION OF SYMBOLS

	Manufacturer	IVD	In vitro diagnostic medical devices
30°C 4°C	Temperature limit		Date of manufacture
LOT	Batch code		Validity period
	Warning		No reusing
	See instructions for use		

REFERENCES

1. Li, etc., Early Transmission Dynamics in Wuhan, China of Novel Coronavirus– Infected Pneumonia, DOI: 10.1056/NEJMoa2001316.

2. Li Taisheng, Peking Union Medical College Hospital's Proposal for Diagnosis and Treatment of "Novel Coronavirus Infected Pneumonia" (V2.0), Union Medical Journal, 2020.1.27.

3. Wei Qiuhua, Disinfection measures for pneumonia epidemic sources of novel coronavirus infection in 2019, Chinese Journal of Disinfection, 2020 (37) 1,59-62.

Made in the USA

For prices and purchase orders in USA and Latin America

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