2019-nCoV IgG/IgM Test Cassette

(Whole Blood/Serum/Plasma)

INTENDED USE

2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019 coronavirus in human whole blood, serum, or plasma as an aid in the diagnosis of 2019 coronavirus infections.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by SARS-CoV-2, [1] a virus closely related to the SARS virus.[2] [3] [4] The disease is the cause of the 2019–20 coronavirus outbreak. It is primarily spread between people by small droplets from infected individuals when they breathe or cough.Time from exposure to onset of symptoms is generally between 2 and 14 days.

IgM is the first antibody to appear in the human immune system. It usually appears within a week, and IgG antibodies appear within 2-4 weeks. Detection of new coronavirus IgM with human blood in the acute infection period, therefore, detection of new coronavirus IgM, IgG antibodies has important clinical significance for effective control of the scale of the new coronavirus.

2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of 2019-nCoV antigen coated colored particles for the detection of IgG and IgM 2019-nCoV antibodies in human whole blood, serum, or plasma.

PRINCIPLE

2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of 2019-nCoV 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 test line region 1 of the test. During testing, the specimen reacts with 2019-nCoV antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in test line region 1. If the specimen contains IgG antibodies to 2019-nCoV, a colored line will appear in test line region 1. In the IgM component, anti-ligand is coated in test line region 2 of the test. During testing, the specimen reacts with ligand anti-human IgM. 2019-nCoV IgM antibodies, if present in the specimen, reacts with the ligand anti-human IgM and the 2019-nCoV antigen-coated particles in the test strip, and this complex is captured by the anti-ligand, forming a colored line in test line region 2.

Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in test line region 1. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in test line region 2. If the specimen does not contain 2019-nCoV 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.

REAGENT

The test cassette contains2019-nCoV antigen-coated particles and ligand anti-human IgM. Anti-human IgG and anti-ligand are coated in the test line regions.

MATERIALS

Materials Provided

- Individually packed test cassette
- Disposable pipettes
- Package insert
- Buffer

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Micropipette
- Timer
- Lancets

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date. Do not reuse tests.
- Do not eat, drink or smoke in the area where the specimens or Cassettes are handled.
- Do not use the test if the pouch is damaged.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The cassette should be stored at 2-30 ℃ until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the Cassette from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

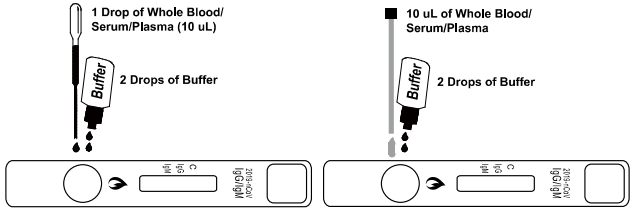
SPECIMEN COLLECTION AND STORAGE

- 2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 ℃ for up to 3 days. For long term storage, specimens should be kept below -20 ℃. Whole blood collected by venipuncture should be stored at 2-8 ℃ 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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

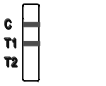
TEST PROCEDURE

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

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within an hour.
2. Place the test cassette on a clean and level surface.
   Hold the dropper vertically, draw the specimen and transfer 1 drop of whole blood/serum/plasma (approximately 10 µL) to the specimen well of the test cassette, then add 2 drops of buffer (approximately 70 uL) to the specimen well of the test cassette and start the timer. Avoid trapping air bubbles in the specimen well See illustration below. To use a micropipette: Pipette and dispense 10 µL of whole blood/serum/plasma to the specimen well of the test cassette, then add 2 drops of buffer (approximately 70 µL) to the specimen well and start the timer.
3. Wait for the colored line(s) to appear. Read results at 15-20 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

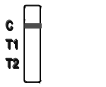


IgG POSITIVE:* The colored line in the control line region (C) appears, and a colored line appears in test line region 1 (T1). The result is positive for 2019-nCoV virus specific-IgG.

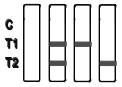
IgM POSITIVE:* The colored line in the control line region (C) appears, and a colored line appears in test line region 2 (T2). The result is positive for 2019-nCoV virus specific-IgM antibodies.

IgG AND IgM POSITIVE:* The colored line in the control line region (C) appears, and two colored lines should appear in test line regions 1 and 2 (T1 and T2). The color intensities of the lines do not have to match.

***NOTE:** The intensity of the color in the test line region(s) (T1 and/or T2) will vary depending on the concentration of 2019-nCoV antibodies in the specimen. Therefore, any shade of color in the test line region(s) (T1 and/or T2) should be considered positive.



NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions 1 or 2 (T1 or T2).



INVALID: No colored line in the control line region (C) appears. 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 Cassette immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appears in the control line region (C), confirming sufficient buffer volume and adequate membrane wicking.

Control standards are not supplied with this Cassette; 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 OF THE TEST

1. 2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of 2019-nCoV antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in 2019-nCoV antibody concentration can be determined by this qualitative test.
2. 2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of 2019-nCoV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCoV.
3. In the early stage of the infection, anti-2019-nCoV IgM concentrations may be below detectable levels. For primary infection, an IgM antibody-capture enzyme-linked immunosorbent assay (MAC-ELISA) showed that 80% of the 2019-nCoV patients tested exhibited detectable levels of IgM antibody by the fifth day after infection, and 99% of the patients tested IgM positive by day 10.It is recommended that patients be tested within this time.
4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
5. atchResults from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of 2019-nCoV infection.

EXPECTED VALUES

Primary 2019-nCoV infection is characterized by the presence of detectable IgM antibodies 3-5 days after the onset of infection. Secondary 2019-nCoV infection is characterized by the elevation of 2019-nCoV -specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

2019-nCoV IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with 20 positive specimens and 20 negative specimens obtained from a population of symptomatic and asymptomatic individuals.

For the primary and secondary infection, the overall sensitivity is 95%, the overall specificity is 95% and the overall accuracy is 95%.

LITERATURE REFERENCES

1. Naming the coronavirus disease (COVID-19) and the virus that causes it". www.who.int. World Health Organization. Archived from the original on 28 February 2020. Retrieved 28 February 2020.
2. World Health Organization (11 February 2020). Novel Coronavirus (2019-nCoV): situation report, 22 (PDF) (Report). World Health Organization.
3. Gorbalenya AE (11 February 2020). "Severe acute respiratory syndrome-related coronavirus – The species and its viruses, a statement of the Coronavirus Study Group". bioRxiv: 2020.02.07.937862. doi:10.1101/2020.02.07.937862. Archived from the original on 11 February 2020. Retrieved 11 February 2020.
4. Coronavirus disease named Covid-19". BBC News. 11 February 2020. Archived from the original on 11 February 2020. Retrieved 11 February 2020.

GLOSSARY OF SYMBOLS

CE Approved

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

Prometheus Bio Inc.
Room 206, Building 7, No. 368 Road 12,
Hangzhou Economic & Technology
Development Zone, Zhejiang
Province, China 310018

EC REP
Wellkang Ltd
Suite B,29 Harley Street
LONDON W1G 9QR,England,
United Kingdom

Date of issue: 2020/03/05