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 immunochromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019 coronavirus in human whole blood, serum, or plasma.

INDICATIONS

Coronavirus disease 2019 (COVID-19) is an infection caused by SARS-CoV-2, a virus closely related to the SARS virus. The disease is the cause of the 2019-20 coronavirus outbreak. It is primarily spread among people by droplets from infected individuals when they breathe or cough. The test is often used to detect the virus in samples from patients with respiratory symptoms. During testing, the specimen reacts with human blood in the acute infection period, therefore, detection of new coronavirus IgG/IgM antibodies has important clinical significance for effective control of the scale of the new coronavirus.

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

PRINCIPLE

2019-nCoV IgG/IgM Test Cassette (Whole Blood/Plasma/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 membranes, an IgG antigen component, and an IgM antigen component. The IgM antigen is coated in test line region 1 of the test. During testing, the specimen reacts with 2019-nCoV antibodies in the test. The mixture then migrates upward on the membrane chromatography by capillary action and reacts with the anti-human IgM in test line region 1. If the specimen contains 2019-nCoV antibodies to 2019-nCoV, a colored line will appear in test line region 1. In the IgG component, anti- IgG is coated in test line region 2 of the test. During testing, the specimen reacts with human anti-IgG and 2019-nCoV IgG antibodies, if present in the specimen, with the IgG specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM. The species and its viruses, a report, 22 (PDF) (Report). World Health Organization.

The test cassette contains 2019-nCoV antigen-coated particles and liquid anti-human IgM Anti-human IgG and anti-coated IgG are coated in the test regions.

MATERIALS

Materials Provided
- Individually packed test cassette
- Disposable pipettes
- Package insert
- Buffer
- Timer
- Micropipette

Materials Not Provided
- Specimen collection container
- Centrifuge

PRECATIONS

- For professionals in vitro detection use only. Do not use after the expiration date. Do not reuse tests.
- Do not 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 processed.
- The used test should be discarded according to local regulations.
- Humidity and temperature changes can adversely affect results.

STORAGE AND STABILITY

- The test cassette should be stored at 2-30°C 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°C for up to 7 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 it 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 specimen for more than 3 times.
- If specimens are to be shipped, pack in compliance with all applicable regulations for transportation of biological specimens.
- Icteric, hemolyzed, 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°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 an hour.
2. Place the test cassette on a flat and level surface. Hold the dropper vertically, draw the specimen and transfer 1 drop of whole blood/serum/plasma (approximately 10 µL) to the well of the test cassette, then add 2 drops of buffer (approximately 70 µL) to the specimen well 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 blood specimen into the test cassette well. 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 15-30 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 (IgG). 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 (IgM). The result is positive for 2019-nCoV virus specific IgM.
- 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 (IgG and IgM). The color intensities of the lines do not have to match.

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

INVALIAD: 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 that the test cassette and procedural techniques are working. 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 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/Plasma/Plasma) will only indicate the presence of 2019-nCoV antibodies in the specimen and should not be used as the sole basis for diagnosis of 2019-nCoV.
3. The continued presence or absence of antibodies cannot be used to determine the effectiveness or failure of therapy.
4. Additional tests 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. 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.
7. This test has not been reviewed by the FDA.
8. 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. 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. This test is not intended for use in home use.
10. Positive results may be due to past or present infection with non-SARS-CoV-2 coronaviruses strains, such as coronavirus Hku-1, NL63, OC43, or 229E.

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 37 positive specimens and 61 negative specimens obtained from a population of symptomatic and asymptomatic individuals.

For the primary and secondary infection, the overall sensitivity is 89.2%, the overall specificity is 100% and the overall accuracy is 99.6%.

LITERATURE REFERENCES


GLOSSARY OF SYMBOLS

CE Approved
Catalog number
Consult Instructions for use
Temperature limitation
In vitro diagnostic medical device
Manufacturer
Use by
Batch code
Do not re-use

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