Vazyme
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2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based) Instruction for Use (Version 1.0)

PRODUCT NAME

2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based).

CATALOG NUMBER & SIZE

10 tests / kit, 50 tests / kit.

INTENDED USE

This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). It is suitable for qualitative detection of IgG / IgM antibodies in human serum, plasma, and whole blood.

2019-Novel Coronavirus belongs to the new coronavirus of the genus β, which has an envelope, the particles are round or oval, often polymorphic, and the diameter is 60-140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). After infection with 2019-nCoV, the common symptoms are fever, fatigue, dry cough, dyspnea etc. Some severe patients appear the symptoms including acute respiratory distress syndrome, septic shock, metabolic acidosis that is difficult to correct, and coagulation disorders. Some patients have mild symptoms and no fever. Most of patients have a good prognosis, while a few are in critical condition or even die.

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. The level of IgM antibody begins to rise within 1 week and achieves the peak at 2-3 weeks after the initial infection. While the IgG appears later than IgM (usually in 14 days after infection) and achieves the peak at 5 weeks, lasting for 6 months or even several years. When the antibody titer of patients in the convalescence period is 4 times (or more than 4 times) higher or lower than that in the acute period, which has clinical diagnostic significance for virus infection.

PRINCIPLE OF DETECTION

This product is based on capture and solid-phase immunochromatography methods for determination. The specimen (whole blood / serum / plasma) flows from the blood separator through to the conjugate release pad (which occurs the conjugation reaction between IgM / IgG antibody in the specimen and the antigen colloidal gold of 2019-nCoV to form an immune complex of IgM / IgG antibody and colloidal gold-labeled antigen) due to capillary action. Then migrate to a capture zone of nitrocellulose membrane-immobilized antibody (mouse-anti-human IgM antibody, T1 line) to form an immune complex of colloidal gold-labeled antigen, IgM antibody and mouse-anti-human IgM antibody, thereby generating a T1 red line. The unreacted immune complex continues to flow upward, will be captured by the mouse-anti-human IgG antibodies (T2 line) to form an immune complex of colloidal gold-labeled antigen, IgG antibody and mouse-anti-human IgG antibody, thereby generating a T2 red line. The remaining uncaptured immune complex moves upward, combining with C line (quality control line) to indicate the completion of this reaction.

Components

Components	Ingredients
Test Cassette	Aluminum foil pouch, desiccant, test strip and plastic card. Test strip composing blotting paper, nitrocellulose membrane, specimen separator, colloidal gold-labeled pad and PVC. T1 line (Test line) coating 1.0 mg/mL mouse-anti-human IgM antibody. T2 line (Test line) coating 1.0 mg/mL mouse-anti-human IgG antibody. C line (quality control line) coating 1.0 mg/mL actin protein C. Conjugate release pad containing 40 OD 2019-nCoV antigen-colloidal gold conjugate complex.
Specimen Dilution	HEPES Buffer containing casein (0.1 M), 5 mL/bottle.
Dropper	According to different packing specifications: 10 droppers /pack, 50 droppers/pack.

Note: Do not interchange the components from different batches.

STORAGE & SHELF LIFE

This kit should be stored at 4°C~30°C for 18 months in a sealed condition. Once the inner packaging of strip is opened (4°C~30°C, humidity < 65%), it must be used in 1 hour.

SAMPLING & HANDLING

1. Suitable specimen type: serum, plasma, and whole blood.

2. Sediment and suspended matter in the specimen may affect the test result. It should be removed by centrifugation at 3000 g for 10 minutes.

3. Severe hematolytic, lipemic and turbid specimens should not be used.

4. Whole blood/plasma specimens can be treated with heparin sodium or EDTA anticoagulant. After specimen collection, the test should be completed within the same day. If not, please store it as the following protocol:

For whole blood specimens, store at 2℃ ~8℃ for 3 days.

For Serum/plasma specimens, store at 2℃ ~8℃ for 7 days, or at < -20℃ for 12 months.

5. Specimens must be fully restored to room temperature (18℃ -28℃) before testing. Freeze-preserved specimens should be completely melted, reheated and mixed thoroughly before use.

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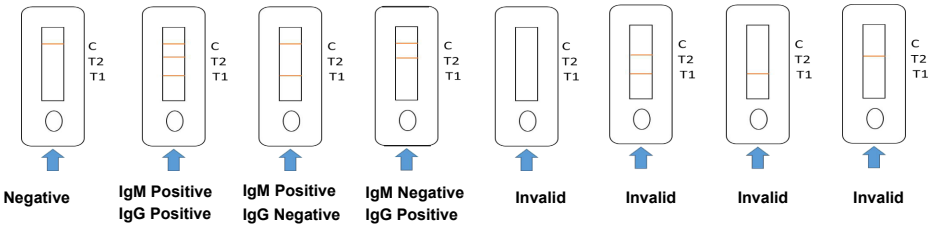
PROTOCOL

Read the instructions carefully before operating.

1. Fully incubate the test strips at room temperature before use. The test must be operated at room temperature.
2. Remove the test strips from the aluminum foil pouch and place it on a horizontal and dry table.
3. Dilute the serum, plasma and whole blood specimens, using provided dropper sampling to add 1 drop (about 20 μL) to the sample loading position, then open the black cap of the drop bottle, add 2-3 drops of dilution buffer(about 60 μL)to the sample loading position. Start timing.
4. Observe the test card after 10 minutes and analyze the results.

INTERPRETING TEST RESULTS



The test results are analysed as follows:

1. Negative result: Only one red quality control line (C line) appears in the detection area.
2. IgM positive, IgG positive result: Three clear red lines appear in the detection area, one is quality control line (C line), one is T2 detection line, and the other is T1 detection line.
3. IgM positive, IgG negative result: Two clear red line appear in the detection area, one is quality control line (C line) and another is T1 detection line.
4. IgM negative, IgG positive result: Two clear red line appear in the detection area, one is quality control line (C line) and another is T2 detection line.
5. Invalid result: No red quality control line (C line) appears in the detection area (e.g. without any red lines or only test lines (T1, T2 line)), indicating that the test error or the test result is invalid, and the test should be retested.

LIMITATIONS OF TEST METHODS

1.The test results of this product are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment.

The clinical management of patients should be considered in combination with their symptoms / signs, medical history, treatment reactions and epidemiology and other laboratory tests.

It is recommended to repeat the test for suspicious samples at intervals.

2. The accuracy of detection is affected by the sample collection process. Improper sample collection and storage process will affect the test results and should avoid high temperature and direct sunlight.
3. This production provides a qualitative test for the novel coronavirus IgM antibody and IgG antibody in the sample, but not quantified detection.
4. Due to the limitation of the testing methodologies, it cannot ruled out the possibility of the novel coronavirus infection based on negative results. It is recommended to combine other test results and clinical symptom to make an accurate diagnosis.

PRODUCT PERFORMANCE INDICATOR

1. Sensitivity: Test with the enterprise's sensitivity reference product.
2. Conformity rate of Negative Control: Test with the enterprise's negative reference product and the test results are all negative for the 2019-nCoV IgG / IgM antibody, with a conformity rate of 100%.
3. Conformity rate of Positive Control: Test with the enterprise's positive reference product and the test results show that the PC01-PC05 and PC11-PC15 of 2019-nCoV IgG antibodies are positive, with a conformity rate of 100%; the PC06-PC15 of 2019-nCoV IgM antibody are positive, with a conformity rate of 100%.
4. Repeatability: Test with the enterprise's repetitive reference product and the test results are positive for the 2019-nCoV IgG / IgM antibody, with uniform color rendering.
5. Difference between batches: Test for the enterprise's repetitive reference product and the test results show that three batches of the kits are all positive, with uniform color rendering.

NOTE

1. This kit is only for in vitro diagnosis.
2. It should be operated by professionally trained inspectors, read the product manual carefully before operation, and conduct the test operation strictly in accordance with the kit instructions.
3. Protective measures against infectious diseases should be took. Thorough sterilization must be done after operation of handling reagents and specimens.
4. Keep it clean and treat the pollutants as wastes. The waste treatment should be performed in accordance with WS / T249-2005 "Clinical Laboratory Waste Disposal Principles" for the safe disposal of waste and the safe disposal of infectious waste. Please handle with care.

REFERENCES

1. Hui DS, et al. (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China. International Journal of Infectious Diseases, 91, 264–266.

2. Templeton KE, et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4. Journal of clinical microbiology 42(4): 1564-1569.

3. Smith AB, et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR. Journal of Clinical Virology 28(1): 51-58.

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DATE OF APPROVAL AND MODIFICATION OF INSTRUCTION

February 27th, 2020

DATE OF MANUFACTURE AND EXPIRATION

See packaging.

Symbols

EC REP	Authorized Representative
IVD	For in vitro diagnostic use only
30°C 4 °C	Store between 4-30°C

Σ	Tests per kit
REF	Catalog #
LOT	Lot Number

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