2019-nCoV IgM /IgG Antibody

Catalog No.: LIVO CT300

Packing specification

20 test cards/ box

Intended Use

This kit is used to qualitatively detect the existence of IgM and IgG antibodies against 2019 novel coronavirus(2019-nCoV) in serum, plasma or whole blood samples. Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). It was discovered that coronavirus 2019-nCoV causes coronavirus disease COVID-19 most recently.

Principles of the Tests

This kit is established with a colloidal gold immunochromatography technique for the rapid detection of IgM and IgG antibodies against 2019-nCoV in serum, plasma or whole blood samples. The colloidal gold labeled recombinant Np Ag and mouse IgG colloidal gold marker are immobilized on the conjugate pad, mouse anti human IgM monoclonal antibody （μ） and mouse anti human IgG monoclonal antibody （γ） was pre-coated on the detection line (T) position on the nitrocellulose membrane respectively. The control line(C) was coated with goat anti-mouse IgG polyclonal antibody. When an appropriate amount of samples to be tested is added to the sample well of the test cassette, the sample will move forward by chromatography. If the sample contains antibodies against the 2019-nCoV, the antibodies can combine with colloidal gold labeled recombinant Np Ag to form an immune complex. The immune complex will flow forward undergoing the inside of the nitrocellulose membrane, and will be caught by the coated mouse anti human IgM antibody （μ）or anti human IgG antibody （γ） to develop color when it passed the T line position. The free colloidal gold marker will be caught by the goat anti-mouse IgG polyclonal antibody coated on the C line to develop color. Negative samples develop color only at the C line.

Main Constituent

1.Test cassette(T1 line coated with mouse anti human IgM antibody （μ） ,T2 line coated with mouse anti human IgG antibody （γ） ,C line coated with goat anti-mouse IgG polyclonal antibody): 20 test cards/ box
2.Sample diluent (0.05mol/L PBS pH7.4): 1 bottle (3 ml)
3.Product instruction: 1

Storage conditions and the period of validity

Store at 4～30℃, dry places for 24 months. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.

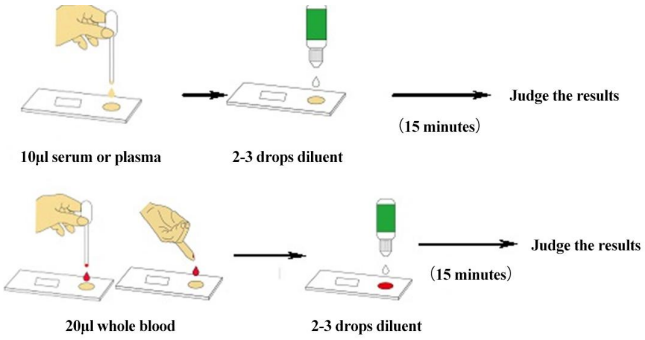
Sample Request

1. Serum and plasma samples were collected from the venous blood by conventional method. Plasma sample: add 100ul heparin solution (1%) to 5 ~ 10ml blood; or sodium citrate solution (3.8%) to plasma according to the proportion of 1:9; or EDTA solution (15%) 0.04ml to 5ml plasma.
2. Serum and plasma samples can be stored at 2 ~ 8 ℃ ℃ if tests will be done within 5 days, otherwise stored at -20 ℃. No more than 3 times of freeze-thaw.
3. It is recommended to test the whole blood samples within 3 days. Store the samples at 2 ~ 8 ℃. Do not freeze.
4. For samples containing suspended fibrin or polymer, it is recommended to take the supematant fluid for testing after centrifugation. Hemolytic samples cannot be tested.
5. There should be no other microbial contamination in the sample to be tested.
6. Specimen transfer boxes should be specially marked. After removing the specimen from the sealed bag, it should be disinfected by UV or 75% ethanol spray.
7. Please equilibrate the samples to be tested at room temperature for more than 30 minutes before use. Mix the frozen samples before testing.

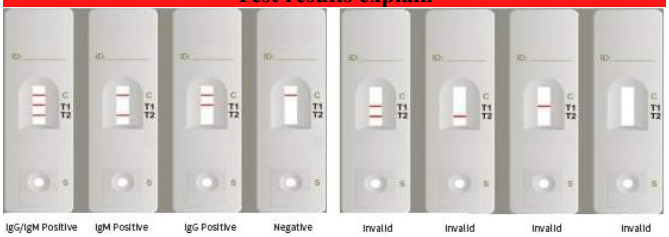
Test Procedure

1. Test preparation: 10μL, 50μL ,100μL micropipettes and matched tips

2. Test process: The temperature of the kit and the test sample should be the same with room temperature before test. Place the test card on a dry horizontal work surface. Add 10μL serum or 20μL whole blood sample into the sample well, then add two drops(about 70~100μL) of sample dilution immediately. Observe the result in 10~15 minutes after the serum or plasma samples added. The observation is invalid after 15 minutes.



Test results explain



Negative: If only the C line is present, the absence of any color in the T1 and T2 line indicates that no anti-2019-nCov antibodies are detected. The result is negative.
Positive:

In addition to the presence of C line, if only T1 line is developed, the test indicates for the presence of anti-2019-nCov IgG. The result is positive;
In addition to the presence of C line, if only T2 line is developed, the test indicates for the presence of anti-2019-nCov IgM. The result is positive;
In addition to the presence of C line, both T1 line and T2 line are developed, the test indicates for the presence of anti-2019-nCov IgM and IgG. The result is positive;
Invalid:
If no C line is developed, the assay is invalid regardless of any color in the T1 line and T2 line as indicated below. Repeat the assay with a new device. If the problem persists, stop using this lot immediately and contract with your local supplier.
Note: Re-detection if the detection result is invalid. The invalid test cards should be dealt as infectious pollutants. The temperature of the kit and the test sample should be the same with room temperature before pre-detection.

Limitation

1. It was vulnerable to the visual error or subjective judgment factors. Duplicating detection when a stripe color is not obvious.
2. The detection card is one of the assistant diagnostic methods. Its test results are only for reference and should not be the sole basis for clinical diagnosis and treatment. The positive results should be further verified by other methods. Due to the limit of detection sensitivity, the negative results may be observed because the concentration of antibodies is lower than the analysis sensitivity. The clinical diagnosis should combine with the clinical diagnosis, medical history and other detection methods.
3. The results are unreliable to the patients with impaired immune function or immunosuppressive treatment.
4. Positive is not only occurs in the primary infection, but also in secondary infection.
5. This kit is a qualitative test and cannot used to determine antibody levels.
6. For the test of serum or plasma samples only, not for saliva, urine or other body fluids testing.

Product performance indicators

Positive coincidence rate: to internal reference (+/+) =5/5; Negative coincidence rate (-/-) =10/10; Precision (n=10): positive for all tests, and develop color equably; Minimum detection limit: positive end point is not less than 1:8 dilution of positive reference.
There is impact in test when the lipid content of the sample is higher than 6mmol / L and the bilirubin level is higher than 40μmol / L.

Patients with impaired immune function or receiving immunosuppressive therapy have limited reference values for serological testing.

Rheumatoid factor(≤54IU/mL), respiratory syncytial virus IgM, IgG antibodies; parainfluenza virus IgM, IgG antibodies; Mycoplasma pneumoniae IgM, IgG antibodies; cytomegalovirus IgM, IgG antibodies; herpes simplex virus type II IgM, IgG antibodies positive samples will not affect the test results.

Precautions

1. It needs other methods to confirmation when the kit test result is positive.
2. To avoid the test card exposing in the air long time since it can absorb moisture and affect the test results. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.
3. The degree of coloration on the test line do not inherently connected to the antibody titers in test sample.
4. Be attention to the potential biological risks. Wearing necessary protective equipments, and dealing with waste as infectious material.
5. For clinical reference only, and cannot be used as a basis for confirming or excluding cases alone.

Literature References

1. T. Phan. Novel coronavirus； From discovery to clinical diagnostics. [J]. Infection, Genetics and Evolution,2019.
2. Wassenaar Trudy M, Zou Ying.2019-nCoV: Rapid classification of betacoronaviruses and identification of traditional Chinese medicine as potential origin of zoonoticcoronaviruses.[J]. Letters in applied microbiology,2020.