Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

Instruction for use

【Product Name】

Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

【Packing Specifications】

1 test/bag, 1 test/box, 20 tests/box, 50 tests/box.

【Intended Use】

This kit uses immunocolloidal gold chromatography to detect novel coronavirus IgM/IgG antibodies in human serum, plasma or whole blood in vitro.

The 2019 novel coronavirus, abbreviated as 2019-nCov, is a new strain of coronavirus discovered in the human body and outbreaked in Wuhan in the end of 2019. The symptoms of the virus are fever, fatigue, dry cough, and progressive dyspnea. In severe cases, the symptoms are acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction that can't be reversed. The virus has been confirmed the capacity of human-to-human transmission; the shortest incubation period of the virus is only 1 day, while the longest is 14 days. The patients in incubation period is contagious and there is no specific treatment for the disease. Once infected with a new virus, the body's immune system will start to defend and produce specific antibodies. Generally, IgM antibody will appear in 1-2 weeks and IgG antibody will appear in 4 weeks.

【Principle of the Procedure】

This product adopts the method of immunochromatography, the detection card contains colloidal gold labeled novel coronavirus recombinant antigen and gold labeled rabbit IgG antibody, and is coated with the mixture of anti-human IgM and anti-human IgG in the nitrocellulose-membrane detection line. The quality control line is coated with goat anti-rabbit IgG. When testing, if there is a novel coronavirus antibody in the sample, then the "(novel coronavirus antigen colloidal gold)-(coronavirus antibody)-(anti-human IgM/IgG)" complex is formed in the nitro cellulose membrane detection line to coagulate and display color, indicating a positive result. In the absence of antibodies to the novel coronavirus in the sample, the complex formed is insufficient to coagulate to produce color, indicating a negative result.

The product adopts the solid phase colloidal gold immunochromatographic technology. The detection cassette contains the gold-novel coronavirus recombinant antigen conjugate and the gold-rabbit IgG conjugate. The Test Line (anti-human IgM and anti-human IgG) and the Control Line (Goat anti rabbit IgG) are pre-coated on the surface of the NC membrane. When sample added, if there are enough antibodies to novel coronavirus， it migrates through the conjugate pad, reconstitutes and mixes with the colloidal gold-antigen conjugates. The mixture continues to migrate through the NC membrane to the anti-human IgM and anti-human IgG that present on the membrane. A red line will be visible in the strip, indicating a positive result. If antibodies to novel coronavirus are absent, or are present at very low level, then no color will appear in the Test Line, indicating a negative result.

【Materials provided】

1. Detection cassette: coated novel coronavirus recombinant antigen colloidal gold, rabbit IgG colloidal gold, anti-human IgM, anti-human IgG, Goat anti-rabbit IgG
2. Instruction for use (1 copy)
3. Sample diluent. The main component is phosphoric acid buffer
4. Materials required but not provided: sampler, timer and blood collector.

【Storage Requirements and Validity】

4 ~ 30℃ storage in dark and dry, the validity is tentatively 12 months.

Freezing or use after expiration is prohibited.

Production date and expiry date are shown on the packaging label.

【Sample Requirements】

(1) This kit can be used for the detection of serum, plasma or whole blood.

(2) Serum and plasma specimens can be stored at 2~8℃ for up to one week from time of draw, or at frozen (<-20℃) and avoid repeated freezing and thawing; whole blood samples must be fresh.

(3) Whole blood and plasma sample can be prepared with EDTA, heparin or sodium citrate as anticoagulant.

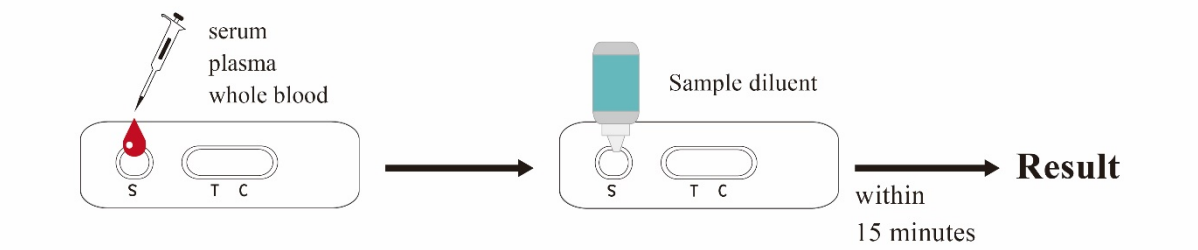
【Test Procedure】

Read the Instruction for use thoroughly before test and equilibrate all reagents kit and samples to room temperature before testing.

1. Take out a test cassette from a foil pouch before use, and place it on a flat surface. Test reagents should be used as soon as possible after the foil bag is opened.

2. Use the pipette to absorb 10uL sample, add it into the sample hole, and add two drops (about 70uL) diluent immediately.

3. Observe the results within 15 minutes after sample addition.

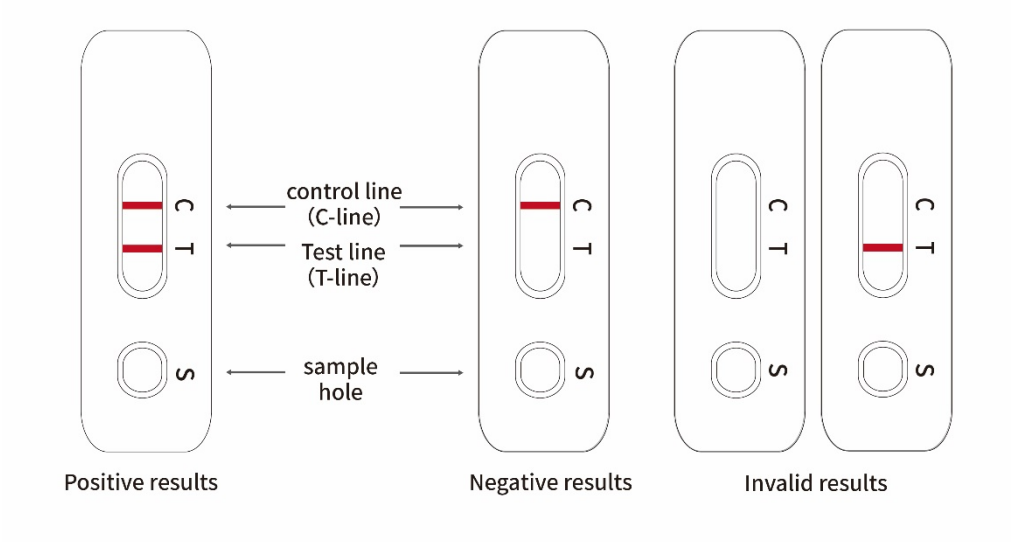


【Cutoff for Test】

Judging by visual observation results:

Positive result: A red strip (regardless of the depth of color rendering) can be observed with the naked eye at test line

Negative result: No red strip can be observed with the naked eye at test line.



【Interpretation of Results】

Positive results: A red strip appears both on the control line (C-line) and the test line (T-line) of the cassette.

Negative results: A red strip appears only at the control line (C-line) of the cassette.

Invalid results: no red strip appeared on the test line or the control line of the cassette, or only a red line appeared on the test line, but no strip appeared on the control line.

Description of test results:

1. When the test results show "negative", but relevant symptoms still occur, it is recommended to conduct further examinations in time to confirm the cause.
2. When the test results show "positive", it is recommended to conduct further review immediately.

【Limitations of the Procedure】

1. This reagent is only used to detect IgM/IgG antibodies against novel coronavirus in human serum, plasma or whole blood/finger samples. Other body fluids and samples may not get correct results.
2. The reagent is a qualitative reagent.
3. Follow the instruction for use strictly for the test.
4. The test results obtained by other methods are not directly comparable with that of this product.
5. The test results of this kit are for reference only and shall not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment responses.
6. There may be suspicious results due to the operation and samples. At this time, repeated tests should be conducted to ensure the consistency of the results.

【Product Performance Indicators】

1. Negative reference: to test the negative reference of enterprises, the test results should be all negative, that is, the coincidence rate of negative is 100%
2. Positive reference: the enterprise positive reference should be tested, and the test results should be all positive, that is, the positive coincidence rate should be 100%.
3. Minimum detection limit: the minimum detection limit reference of the testing enterprise shall be positive.
4. Precision: the precision reference of the enterprise shall be tested for 10 times. The reaction results shall be consistent, and the chromaticity shall be uniform.

【Attentions】

1. This product is only used for in vitro diagnosis. Please read this manual carefully before use.
2. If the aluminum foil bag of test card is found broken, it should be discarded.
3. All samples and materials in the testing process shall be handled in strict accordance with the operating standards of the infectious disease laboratory.
4. Please ensure that sufficient samples are used for testing. Insufficiency may lead to invalid results.
5. This product is visual reading result. In order to ensure the accuracy of the reading result, please do not read the result in dim light.
6. Hemolytic samples should not be used for testing.
7. Samples containing a higher titer of heterophobic antibodies or rheumatoid factors may affect the expected results.
8. This kit is suitable for the initial screening of patients with suspected novel coronavirus, and the final results should be determined by the clinician in combination with clinical symptoms and other laboratory test indicators.

【References】

1. "Pneumonia diagnosis and treatment program for novel coronavirus infection" of the National Health Commission of People's Republic of China (Trial Version 7)

2.World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance

【Manufacturer】

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