COVID-19 IgG/IgM Detection Kit（Colloidal Gold）Instruction

【Product Name】

COVID-19 IgG/IgM Detection Kit（Colloidal Gold）

【Packing specification】

20 tests / kit

【Intended use】

The novel coronavirus is used for the qualitative detection of IgM and IgG antibodies in human serum, plasma or whole blood.

The 7 categories novel coronavirus (HCoV) that can cause respiratory diseases in humans was found: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HcoV-HKU1, MERS-CoV and new coronavirus (COVID-19), and is an important pathogen of human respiratory tract infection. The clinical manifestations were fever, fatigue and other systemic symptoms, accompanied by dry cough and dyspnea. It could rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base disturbance, and even endanger life.

However, when the human is infected by the novel coronavirus, the first antibody produced is IgM antibody, which is generally produced 3-7 days after infection and replaced by a large number of IgG antibodies produced about two weeks later. Therefore, the new coronavirus specific antibody IgM and IgG can be used as an auxiliary means for the diagnosis of suspected patients.

【Test principle】

Immunochromatography is used in this kit. The test card contains:

1. Novel coronavirus antigen novel coronavirus antigen and colloidal gold labeled antibody were used in colloidal gold labeling;

2. Two fixed lines (G line coated with anti human IgG antibody and M line coated with anti human IgM antibody) and a quality control line (C line) of nitrocellulose membrane were used for detection of new coronavirus specific antibodies IgM and IgG; C line fixed quality antibody.

The novel coronavirus will be moved along the detection card when the sample is added to the sample hole of the test card. If the sample contains IgM antibody, the antibody will bind to the colloidal gold labeled new coronavirus antigen. The immune complex will be captured by the immobilized anti human IgM antibody on the membrane, forming a purple red M line, showing the positive IgM antibody of the new coronavirus.

If the antibody contains IgG antibody, the antibody will be captured by the immobilized reagent on the membrane and form the purple red G line, showing that the new coronavirus IgG antibody is positive. If both lines g and M do not show color, negative results will be displayed. The test card also contains a quality control line C. whether there is a test line or not, the purple red quality control line C should appear. The quality control line is the color band of quality control antibody immunoassay. If the quality control line C does not appear, it indicates that the test result is invalid. This sample needs another test card to retest.

【Main composition】

1. Detection card
2. Disposable plastic burette
3. Specimen Diluents (3ml/bottle)
4. Instruction (User manual)

【Storage conditions and expiry date】

1. Store in a dry place at 2-30℃ and away from light.
2. The test card will fail due to moisture absorption after opening the inner package, please use it within 1 hour.
3. Valid for 12 months.

【Applicable machine】

Not applicable.

【Sample request】

1. It is applicable to human serum, plasma or whole blood, including plasma samples prepared by clinical commonly used anticoagulants (EDTA, heparin, sodium citrate).
2. Samples shall be tested immediately after collection. If it cannot be detected immediately, the serum, plasma or whole blood samples to be tested can be stored at 2-8℃ for 5 days. If long-term storage is required, it should be placed at -20℃,and it is avoid repeated freezing and thawing of samples.
3. Before testing, slowly restore the refrigerated or frozen samples to room temperature and mix them carefully. When there is a visible particulate matter in the sample, it should be centrifuged before the test to remove the precipitate.
4. If the sample contains a large amount of lipid, hemolysis or turbidity in the sample, please do not use it to avoid affecting the result judgment.

【Test method】

Step.1 If the sample is refrigerated or frozen, remove the sample to be tested and the required reagent from the storage condition. Equilibrium at room temperature. After melting, thoroughly mix the samples before testing.

Step.2 When preparing for testing, open the aluminum foil bag from the tear opening, take out the test card, and lay it on the horizontal desktop.

Step.3 Mark the sample number on the test card.

Step.4 Take one drop (about 10ul) of the sample (serum, plasma or whole blood) from the sample tube with the pipette or dropper and put it into the sample well on the test cartridge. Immediately add two drops (about 80ul) of sample diluent into the sample well, and ensure that no bubbles are generated during the operation.

Step.5 10 minutes to observe the results.

NOTE: Do not check the results after 15 minutes. After observing and recording the results, please discard the detection card to avoid confusing the result judgment. For long-term preservation, please take photos of the results.

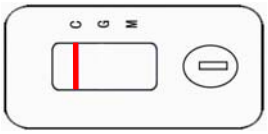
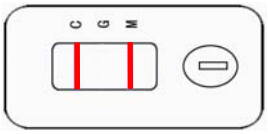
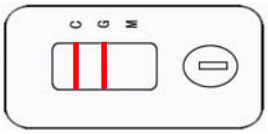
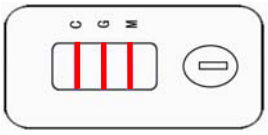
【Positive judgment value】

When the G-line is positive, the result is determined to be IgG positive;

when the M-line is positive, the result is determined to be IgM positive;

when the G-line and M-line are both positive, the result is determined to be IgG and IgM positive.

【Interpretation of test results】

RESULT	ILLUSTRATION
1.Negative result:	
If only QC line C appears, neither detection line G nor M will show color. No novel coronavirus antibody was detected, and the result was negative, as shown below.	
2.Positive result:	
2.1 The novel coronavirus IgM antibody was detected if the quality control line C and the detection line M appeared, and the result was IgM antibody positive, as shown below.	
2.2 The novel coronavirus IgG antibody was detected if the quality control line C and the detection line G appeared, and the result was IgG antibody positive, as shown below.	
2.3 The novel coronavirus IgG and IgM antibodies were detected if the quality control line C and the detection line G and M appeared, and the results were positive for IgG and IgG antibodies, as shown below.	
3. Invalid result:	

• This test has not been reviewed by the FDA.
• 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.
• Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
• Not for the screening of donated blood