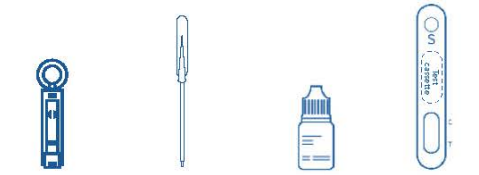
User's Manual

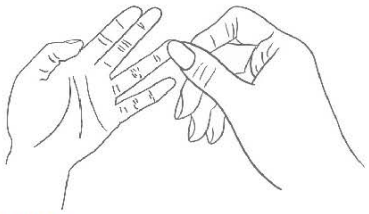
Preparation

Constant temperature: open the carton, pick out the inner package, leave at room temperature, wait for 30mins.

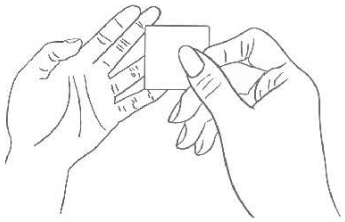


Disposable needle | Disposable micropipette | Diluent | Test cassette

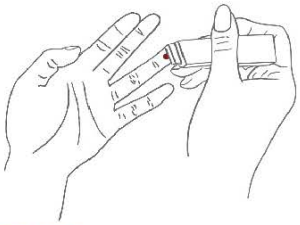
Sample collection



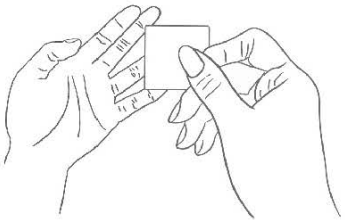
1.Massage
Massage pulp of the left ring finger.



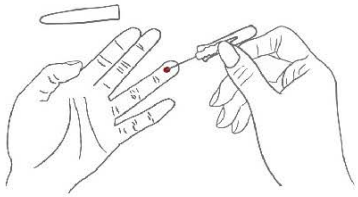
2.Disinfect
Wipe the needle puncture site with alcohol swab.



3.Puncture
Hold the disposable sterile blood collection needle to puncture a depth of 2-3mm on the ventral ulnar side of fingertip by right hand, and then pull out the needle immediately.



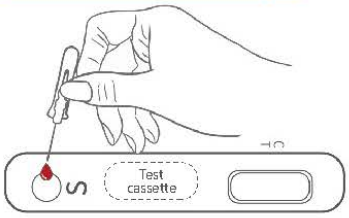
4.Wipe off
After the blood flows naturally, wipe off the first drop with another alcohol swab.



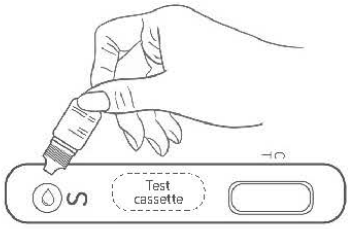
5.Sample collection
Suck blood to the tick mark of the disposable micropipette, and then press wound with alcohol swab to stop bleeding; If the blood flows is not enough, press the left ring finger (from the palm towards the fingertip) slightly to make blood flow out.

User's Manual

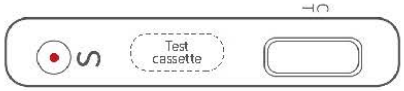
Testing process



1.Load sample
A total of 20μl whole blood was loaded to the sample hole of the test cassette.

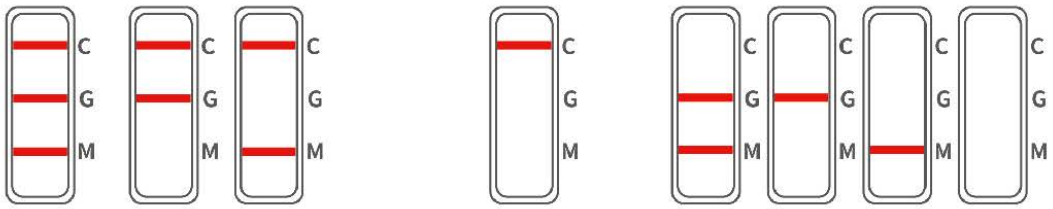


2.Dilute
Load 2-3 drops of the diluent to the sample hole of the test cassette and start the timer.



3.Read
Leave the test cassette at room temperature for 10mins to 20mins, and then read results which will be invalid 20mins later.

Result



Positive | Negative | Invalid

Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19 (Colloidal Gold Immunochromatography Assay) Instruction Manual

[Product Name]

Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus COVID-19(Colloidal Gold Immunochromatography Assay)

[Packaging Specification]

20 tests / Kit.

[Introduction]

The outbreak of the novel coronavirus disease is now a pandemic and a serious public health crisis worldwide. Detection of viral nucleic acid by Real-time PCR is still the gold standard for diagnosis of COVID-19，however, the RT-PCR based tests have showed many limitations in clinical utilization, e.g. Time consuming, relatively high facility requirement and remarkable false negative rate in throat swab sample. There is an urgent need for the introduction of an accurate, easy, and rapid alternative test to identify potential infected individuals. The Diagnostic Kit for Antibody IgM/IgG of Novel Coronavirus was therefore designed to

rapidly detect both IgM and IgG antibodies against the novel coronavirus in human serum, plasma or whole blood in vitro.

This kit used recombined spike (S) protein and nucleocapsid (N) protein of the novel coronavirus as antigen to detect specific IgM and IgG antibodies in human blood samples. IgM antibodies was generally considered to provide the first line of defense during pathogen infections, followed by the production of high affinity IgG antibodies for long term and more effective immunity. Therefore, simultaneous detection of novel coronavirus IgM and IgG antibodies is an effective strategy for the rapid and precise diagnosis of COVID-19. Furthermore, detection of IgM antibodies usually indicates an acute infection of novel coronavirus, whereas detection of IgG antibodies usually indicates a later stage of infection. Thus, this combined test could also provide information on the stage of infection.

[Test Principle]

This kit was based on the colloidal gold immunochromatography technology. In brief, anti-human IgM antibodies, anti-human IgG antibodies and colloidal gold labeled novel coronavirus S/N antigen were coated on nitrocellulose membranes which were then inserted into the test card. Upon binding with their specific IgM and/or IgG antibodies, the gold-labeled antigen and these specific antibodies forms a complex. The complex moves forward along the test strip due to chromatography effect and will be captured by the solid-phase anti-human IgM or anti-human IgG antibody that were

embedded in the detected line and finally show color line.

[Component]

Component	Specification	Packaging	Main components
Test Cassette	20	opaque aluminum foil vacuum packaging	nitrocellulose film, novel coronavirus protein, mouse anti-human IgM antibody, mouse anti-human IgG antibody, goat anti-mouse antibody, tetrachloroauric acid
Microscale Pipette	20	opaque aluminum foil vacuum packaging	high pressure polyethylene
Diluent	20	3mL white transparent drip bottle	phosphate buffer, 3.75% Tween-20

[Storage Conditions and Period of Validity]

Keep kits in a cool and dry place at 2 -30°C. Do not freeze. The individual kits and/or box correctly stored kits are valid for 12 months (see the kit box for expiration information).

[Sample Requirements]

1. The kit is suitable for human serum, plasma, or whole blood samples.

2. Samples should be tested as soon as possible after collection. When an immediate testing is not available, serum/plasma samples can be stored at 2-8°C for 3 days, or at -20°C for 6 months, or below-70°C for 48 months. Freezing and thawing of samples are not suggested although the results were proved to be reproducible using samples with no more than 3 freezing and thawing cycles. It is also suggested that the frozen samples should not be tested until reached room temperature. Whole blood samples must be tested within 8 hours after collection.

[Test Instruction]

1. Pre-reagent preparation: All reagents and samples should reach room temperature before use.

2. Obtain a specimen using standard laboratory protocols.

Using capillary sampler, obtain 20μL of fingerstick or venous whole blood specimen or 10μL of serum or plasma.

3. Dispense the specimen into the Test Cassette sample well.

Ensure that the entire sample is dispensed into the sample well.

4. Dispense 2-3 drops of diluent buffer into the Test Cassette sample well. Remove any air bubbles in the dropper. Test on a level surface at room temperature.

5. Allow test to run for 10 minutes. Read the results by viewing the detection window.

Note: Test results that have run over 20 minutes are invalid.

[Interpretation of Results]

Possible results

Each Test Cassette device has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed.

1. Negative Result

If only the quality control line (C) appears and the detection lines G and M are not visible, then no novel coronavirus antibody has been detected and the result is negative.

2 IgM positive Result

If both the quality control line (C) and the detection line M appears, then the novel coronavirus IgM antibody has been detected and the result is positive for the IgM antibody.

3 IgG positive Result

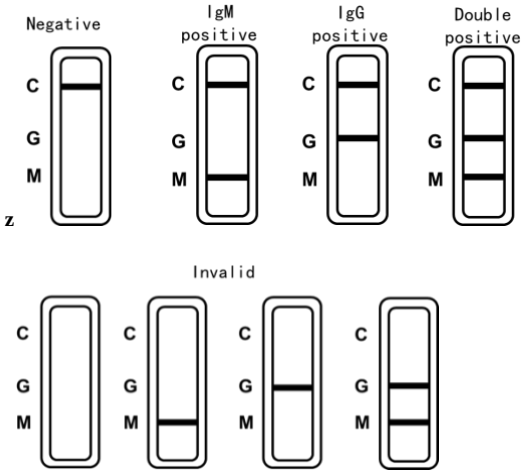
If both the quality control line (C) and the detection line G appears, then the novel coronavirus IgG antibody has been detected and the result is positive for the IgG antibody.

4 Double positive Result

If the quality control line (C) and both detection lines G and M appear, then the novel coronavirus IgG and IgM antibodies have been detected and the result is positive for both the IgG and IgM antibodies.

5. Invalid Result

If the Control line does not appear, the test is invalid regardless the appearance of IgM and IgG lines. In this case, a new test must be performed. If the problem persists, please contact your local vendor for technical support.



[Limitations of the Detection Method]

This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other body fluids or secretions.

This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.

Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.

The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.

Test results can be affected by temperature and humidity.

In patients with impaired immune system or receiving immunosuppressive therapy, the detection of anti-IgM novel coronavirus antibody should be carefully interpreted.

Positive results in people who have recently received blood transfusion should be carefully interpreted.

[Product Performance]

In order to test the detection sensitivity and specificity of this test, blood samples were collected from COVID-19 patients from multiple Chinese hospitals and Chinese CDC laboratories. The tests were done separately at each site.

A total of 370 cases were tested: 188(positive) clinically confirmed (including PCR test) novel coronavirus -infected patients and 182 non- novel coronavirus -infected people (negative). The testing results were summarized in the table below:

	Positive Sample	Non-infected Sample	Total
Sample Quantity	188	182	370
Test Positive	170	0	170
Test Negative	18	182	200
Sensitivity	90.43%		
Specificity		100.00%	
overall coincidence			95.14%

[Reference]

[1] Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China[J]. The Lancet, 2020.

[2] Xu X, Chen P, Wang J, et al. Evolution of the novel coronavirus from the ongoing Wuhan outbreak and modeling of its spike protein for risk of human transmission[J]. Science China Life Sciences, 2020: 1-4.

[3] Chan J F W, Yuan S, Kok K H, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster[J]. The Lancet, 2020.

[4] Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019[J]. New England Journal of Medicine, 2020.

[5] Zhou L, Liu H G. Early detection and disease assessment of patients with novel coronavirus pneumonia[J]. Chinese journal of tuberculosis and respiratory diseases, 2020, 43: E003.