# Instruction of the SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

**【Product Name】**

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)

FOR RESEARCH USE ONLY. NOT FOR DIAGNOSTICS

**【Intended Use】**

This product is used for qualitative detection of IgM and IgG antibodies of SARS-CoV-2 in human serum, plasma, whole blood or fingertip blood in vitro.

In the process of pathogenic microorganism infection, IgG and IgM are the most commonly used antibody markers of infectious diseases. IgM, as the first antibody in the process of infection, is usually used as a marker of acute infection. With the development of infection, IgM concentration gradually decreased and disappeared after the appearance of IgG. IgG usually exists in the body for a long time, even if the virus has been completely eliminated. Positive blood can be used as an indicator of infection and previous infection. Therefore, detecting SARS-CoV-2 IgM antibody and IgG antibody is of great clinical significance and is of great significance for effective control of the large-scale transmission of SARS-CoV-2.

**【Test Principle】**

This product adopts colloidal gold immunity technology, the gold marker of recombinant SARS-CoV-2 antigen and control antibody was sprayed on the binding pad; The nitrocellulosic membrane is coated with two test lines (G and M) and a control line (C). The M-line was coated with mouse anti-human IgM monoclonal antibody, which was used to detect SARS-CoV-2 IgM antibody; The G-wire envelope contains mouse anti-human IgG monoclonal antibody, which is used to detect the SARS-CoV-2 IgG antibody. The C-wire envelope has quality control antibody. When the SARS-CoV-2 sample is added to the sample hole of the test card, the sample will move along the test card under the action of chromatography. If the sample contains the SARS-CoV-2 IgM antibody, the antibody binds to the gold labeled virus antigen. The immune complex forms a sandwich complex with the coated anti-human IgM monoclonal antibody at the M line, showing a purplish red M line, indicating positive IgM antibody for the novel coronavirus. If the sample contains the SARS-CoV-2 IgG antibody, they bind to the gold-labeled SARS-CoV-2 antigen. The immune complex forms a sandwich complex at the G line with the enveloped murine anti-human IgG monoclonal antibody, showing a purplish red G line, indicating that the SARS-CoV-2 IgG antibody is positive. If the test line G and M do not produce color, the negative result is displayed. The test card also contains a control line C. The magenta control line C should be present regardless of whether there is a test line. If the control line C does not appear, it indicates that the test result is invalid, and the sample should be tested again.

**【Main Components】**

(1) Test card: the test card consists of plastic card and strip of paper. The strip is composed of NC membrane (the detection area is coated with mouse anti-human IgG and mouse anti-human IgM antibodies, and the control area is coated with rabbit anti-chicken IgY), combination pad (sprayed with colloidal gold labeling recombinant SARS-CoV-2 antigen and chicken IgY), sample pad, absorbent pad and PVC soleplate

(2) Buffer: 450uL each, buffer containing phosphate (ph6.5-8.0) Dilution Solution

(3) Desiccant: a bag containing silica

Note: The components of different batches of kits can not be used interchangeably

**【Storage And Validity】**

Store the test kit at 2℃-30°C, with a valid period of 12 months. Test strip should be used within 20 minutes once the foil pouch is opened. Production date and expiry date are shown on the label.

**【Sample Requirement】**

1. Apply to serum or EDTA, heparin and sodium citrate anticoagulant plasma/whole blood samples.

2. Immediately after specimen collection, shake up and down 5-10 times, and do not shake with force.

3. The samples should be detected immediately after collection. If they cannot be detected timely, they should be stored at low temperature; Samples can be stored at 2-8℃ for 48 hours and frozen at -20℃ for 3 months.

4. Samples with severe lipid, hemolysis and microbial contamination shall not be used for the test of this product; Obviously turbid samples have an effect on the determination results of this product.

**【Detection Procedures】**

1. The test card, sample and sample diluent should be equilibrated to room temperature(15°C-30°C) before testing.

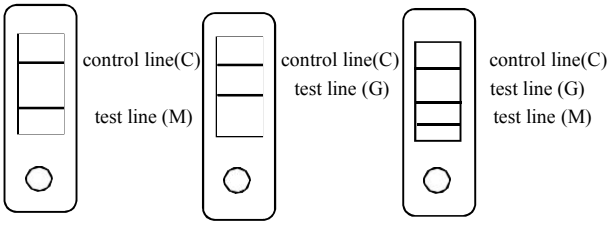
2. Open the aluminum foil bag of the test card, take out the test card and place it horizontally on the desktop.

3. Mix 65ul sample (serum, plasma, or whole blood) with a pipette and mix with the lu e solution, then add 65ul mixture into the sample hole of the test card.

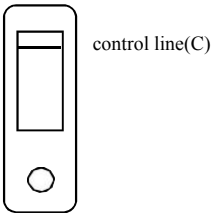
4. Read the esult wi h 15 minutes. And the results read after 18min are invalid.

**【Interpretation Of Result】**

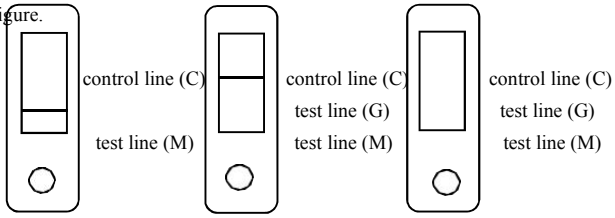
1）Positive r ults: Both the test line (G) and the control line (C) showed color bands, indicating that IgG antibody of the SARS-CoV-2 was positive; Both the test line (M) and the control line (C) showed color bands, and the SARS-CoV-2 IgM antibody was pos t e. The tes ne (M), (G) and control line (C) all showed color bands, and the SARS-CoV-2 IgM and IgG antibodies were positive. As shown in the figure.




2） Negative result: If only the control line C produces color, but the G and M test lines do not, no IgM/IgG antibody of SARS-CoV-2 is detected, and the result is negative. As shown in the figure.




3）Invalid result: No ribbon appears on the control line (C). Invalid result is judged whether the detection line (G) (M) shows the ribbon or not. As shown in the figure.



End User Validation Criteria - Performed by end user.

1. Coincidence rate of negative reference: the negative reference material product compliance rate of the testing enterprise shall be 10/10.

2. Coincidence rate of positive reference: the positive reference material product compliance rate of the testing enterprise shall be 10/10.

3. Minimum detection limit: reference products S1 of the minimum test limit of the testing enterprise shall be negative, and S2 and S3 shall be positive.

1 No detected cross-reactivity was detected as follows: : local human coronaviruses (HKU1, OC43, NL63 and 229E); H1N1 (the new influenza A H1N1 virus(2019), seasonal H1N1)、H3N2、H5N1、H7N9、influenza B Yamagata, Victoria, respiratory syncytial virus, rhinovirus A, B, C groups，adenovirus, 1, 2, 3, 4, 5, 7, 55, enterovirus group A, B, C, D,EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella zoster virus, and mycoplasma pneumoniae samples.

2 Interfering substances: 1) when the bilirubin concentration ≤0.2g/L, hemoglobin content ≤5g/L and triglyceride content ≤10g/L, there will be no interference with the test results of this product. 2) α - interferon, zanamivir, ribavirin, oseltamivir, ceftriaxone, meropenem, ritonavir, abidor, rheumatic factor, anti-nuclear antibody and anti-mitochondrial antibody had no effect on the test results of the product.

**【Limitation】**

1. The kit is only for the detection of human serum, plasma and whole blood samples.

2. Test results may be wrong due to technical reasons, operational errors and other sample factors.

3. In the early stage of infection, if the virus specific IgM antibody is not produced or the titer is very low, it will lead to negative results. If the virus infection is suspected, the patient should be prompted to recheck within 7-14 days. During reexamination, the second sample was taken and tested at the same time with the first sample under the same conditions to determine whether there was serum transformation of the first infection or the titer of virus specific IgM or IgG antibody increased significantly.

4. The test results of this product are only for clinical reference, and should not be the only 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, treatment response, epidemiology and other information.

5. Patients with impaired immune function or receiving immunosuppressive therapy, such as those infected with human immunodeficiency virus (HIV) or receiving immunosuppressive therapy after organ transplantation, have limited reference value for serological IgM antibody detection, which may lead to wrong medical interpretation.

6. Positive test results should be carefully analyzed in persons who have received blood transfusions or other blood products in recent months.

**【Precautions】**

1. Before the test, please balance the sample diluent and the test card to room temperature (more than 30min).

2. The test shall be operated in strict accordance with the instructions.

3. The result must be interpreted within 15min, and the result after 18min is invalid.

4. Do not use repeated freeze-thaw, highly hemolyzed and lipemia samples.

5. The test samples should be regarded as infectious agents, and they must be operated in accordance with the infectious disease laboratory operation rules, and pay attention to biological safety.

6. This product contains animal-derived substances. Although it is not contagious, it should be treated with care as a potential source of infection when handling it. Users should take precautions to ensure their own safety and that of others. After the test, the used test cards, sample dilutions, straws, etc. are treated as biomedical waste.

7. This product is a single-use in vitro diagnostic reagent. Do not reuse it. It is only used for in vitro diagnostics.

8. Do not use kits with obvious damage and damaged test cards in packaging.

9. There is desiccant in the aluminum foil bag, not to be taken orally.

**【Interpretation Of Logo】**

Medical equipment should avoid dampness and keep dry;

Medical devices intended for one-time use or used in a single procedure for a single patient;

Users need to refer to the instructions;

IVD Logo of in vitro diagnostic reagents.

**【References】**

Guidelines for the preparation of in vitro diagnostic reagent specification.