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

【Product Name】

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

【Package Specification】

10 servings/box

25 servings/box

50 servings/box

100 servings/box

【Intended Use】

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

This product is only used as a supplementary detection indicator for suspected cases with negative detection of SARS-CoV-2 nucleic acid or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for diagnosis and exclusion of SARS-CoV-2 pneumonia, and is not suitable for general population screening.

For medical institutions only. A positive test result needs further confirmation. A negative test result cannot rule out the possibility of infection.

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 the SARS-CoV-2.

【Test Principle】

This product adopts colloidal gold immune technology, spraying SARS-CoV-2 recombinant antigen labeled with colloidal gold and chicken IgY on the gold pad; two detection lines (G-line and M-line) and a control line (C-line) are coated on the nitrocellulose membrane. The M-line is coated with mouse anti-human IgM monoclonal antibody, which is used to detect the SARS-CoV-2 IgM antibody. The G-line is coated with mouse anti-human IgG monoclonal antibody for detecting the SARS-CoV-2 IgG antibody. The C-line is coated with rabbit anti-chicken IgY. When testing, an appropriate amount of sample to be tested is added to the sample well of the test card, and the sample will move forward along the test card under capillary action. If the sample contains the SARS-CoV-2 IgM antibody, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen, the immune complex will form a complex with the coated mouse anti-human IgM monoclonal antibody at the M-line, showing a purple-red M-line, suggesting that the SARS-CoV-2 IgM antibody is positive. If the sample contains the SARS-CoV-2 IgG antibody, the antibody binds to the colloidal gold-labeled SARS-CoV-2 recombinant antigen, and the immune complex will form a complex with the coated mouse anti-human IgG monoclonal antibody at the G-line, showing a purple-red G-line, suggesting that the SARS-CoV-2 IgG antibody is positive. If the test G-line and M-line are not colored, a negative result is displayed. The test card also contains a control C-line. The purple-red control C-line should appear regardless of whether a test line appears. If the control C-line does not appear, the test result is invalid, and the sample needs to be tested again.

【Main Components】

(1) Test card: The test card is consists of a plastic card and a test strip. The test strip is consists of a nitrocellulose membrane (the detection area is coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, and the quality control area is coated with rabbit anti-chicken IgY antibody), gold pad (sprayed with colloidal gold-labeled SARS-CoV-2 recombinant antigen and chicken IgY antibody), sample pad, absorbent paper, and PVC board.

(2) Sample diluent: Buffer solution (pH 6.5-8.0) that contains phosphate, corresponding to the specifications of the kit.

Packing specification			
10 servings	25 servings	50 servings	100 servings
450μL/pc* 10 pcs or 2mL/bottle * 1 bottle	450μL/pc* 25 pcs or 4mL/bottle * 1 bottle	450μL/pc* 50 pcs or 8mL/bottle * 1 bottle	450μL/pc* 100 pcs or 16mL/bottle * 1 bottle
See packaging for details	See packaging for details	See packaging for details	See packaging for details

Note: The components in different batches of kits can't be used interchangeably.

【Storage And Validity】

Store the test kit at 2℃-30℃, with a valid period of 6 months. Test strip should be used within 20 minutes once the foil pouch is opened. The date of manufacture and expiry date are shown on the label.

【Sample Requirement】

1. Apply to serum, heparin and sodium citrate anticoagulated plasma, whole blood (EDTA anticoagulated) samples.

2. The samples should be shaken up and down 5-10 times immediately after collection, and should not be shaken with force.

3. Serum, plasma and whole blood samples can be stored at 2-8 ℃ for 7 days; serum and plasma samples can be stored frozen at -20 ℃ for 25 days. It should be returned to room temperature before the test, and the test should be conducted as soon as possible within 8 hours after the sample is collected. The samples should be detected immediately after collection. If the samples cannot be detected timely, they should be stored at 2-8 ℃, and avoid repeated freezing and thawing.

4. Samples with severe lipemia, hemolysis, and microbial contamination cannot be used for the detection of this product; Turbid samples affect the determination results of this product. The use of heat-inactivated samples is not recommended.

【Detection Procedures】

1. If the reagent is removed from the refrigerator, it needs to be restored to room temperature before testing. The test should be performed at room temperature.

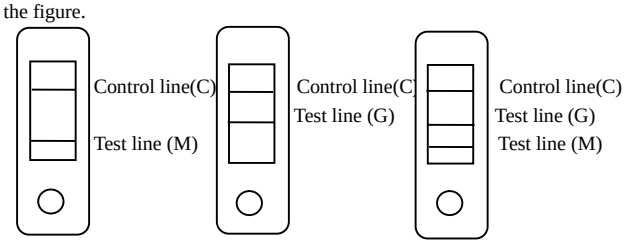
2. Open the aluminum foil bag of the test card, take out the test card and place it on the table horizontally.

3. Use a pipette to aspirate 10μL of the serum, plasma, or 20μL of the whole blood into the sample hole, then use the same method to add 60μL buffer into the sample hole of the test card too.

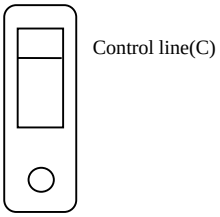
4. Read the result within 15 minutes, and the results read after 18min are invalid.

【Interpretation Of Result】

1) Positive results: Both the test line (G) and the control line (C) show color bands, indicating that IgG antibody of the SARS-CoV-2 is positive; Both the test line (M) and the control line (C) show color bands, indicating that the SARS-CoV-2 IgM antibody is positive. The test line (M), (G) and control line (C) all show color bands, indicating that the SARS-CoV-2 IgM and IgG antibodies are positive. As shown in the figure.



2) Negative result: If only the control line C develops color, and neither the G nor M detection lines develop color, no IgM/IgG antibody of SARS-CoV-2 is detected, and the result is negative. As shown in the figure.



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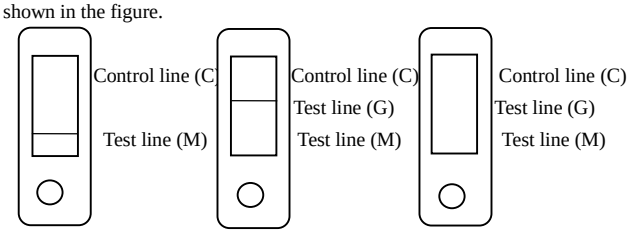
3) Invalid result: No band appears on the control line (C), and it is judged as an invalid result regardless of whether the detection line (G) (M) shows a band. As shown in the figure.



【Performance】

1. Coincidence rate of negative reference: Test negative reference materials of enterprises, the results should be all negative.
2. Coincidence rate of positive reference: Test positive IgM antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgG antibody should be all negative; Test positive IgG antibody reference materials (including strong, medium and borderline positive) of enterprise, the results should be positive, and the results of IgM antibodies should be all negative.
3. Minimum detection limit: Enterprise reference products for the minimum detection limit of IgM antibody, S1, S2 test results should be positive, S3 test results should be positive or negative, IgG antibody results should be negative; Enterprise reference products for the minimum detection limit of IgG antibodies, S4, S5 test results should be positive, S6 test results should be positive or negative, IgM antibody results should be negative.
4. Repeatability: Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.
5. Batch to batch: Test IgM antibody precision reference materials of enterprises, the results should be positive, and the results of IgG antibody should be all negative; Test IgG antibody precision reference materials of enterprises, the results should be positive, and the results of IgM antibody should be all negative.

【Limitation】

1. The kit is only for the detection of human serum, plasma and whole blood samples.
2. The 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 a virus infection is suspected, the patient should be reminded to check again within 7-14 days. During re-examination, the second sample was taken and tested at the same time with the first sample under the same conditions to determine whether there was a 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 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, 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. Those who have accepted blood transfusions or have been treated with other blood products in recent months should be cautious in analyzing their positive test results.

【Precautions】

1. Equilibrate the sample diluent and test card to room temperature (more than 30min) before testing.
2. The test should be performed strictly in accordance with the instructions.
3. The result must be interpreted at 15min, and the result read 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 safety and that of others. After the test is completed, the used test cards, sample diluents, and 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. Do not use expired products.
8. Do not use a kit with obvious damage and damaged test card in the package.
9. There is desiccant in the aluminum foil bag, not to be taken orally.

【Interpretation Of Logo】

CE mark; LOT Batch number; Expiry date;

Date of manufacture; Manufacturer name;

EC REP Name and address of the EC representative;

No direct sunlight; Users need to refer to the instructions;

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;

IVD Logo of in vitro diagnostic reagents.

【References】

Guidelines for the preparation of in vitro diagnostic reagent instructions.

【Bsaic Information】

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【Modification Date】

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