IgM/IgG antibody assay kit for novel coronavirus

(sars-cov-2) User Manual(Immunochromatography)

[PRODUCT NAME]

IgM/IgG antibody assay kit for novel coronavirus (sars-cov-2) (Immunochromatography)

[PACKAGE SPECIFICATION]

10 test/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

This product is used for qualitative in vitro detection of IgM and IgG antibodies against novel coronavirus (sars-cov-2) in human serum, plasma, whole blood or fingertip blood.

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 novel coronavirus IgM antibodies and IgG antibodies is of great clinical significance and is of great significance for effective control of the large-scale transmission of new coronavirus.

[TEST PRINCIPLE]

This product adopts colloidal gold immune technology, spraying colloidal gold labeled recombinant new coronavirus antigen and control antibody gold marker on the binding pad; The nitrocelluum 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 test novel coronavirus IgM antibody. The G - wire envelope contains mouse anti - human IgG monoclonal antibody, which is used to test novel coronavirus IgG antibody. The C - wire envelope has quality - controlled antibodies. When the novel coronavirus 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 novel coronavirus 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 novel coronavirus IgG antibody, they bind to the gold-labeled novel coronavirus 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 novel coronavirus IgG antibody is positive. If the test line G and M do not produce color, the negative result is displayed. The card also contains a control line C. The magenta control line C should appear regardless of whether there is a test line. If 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 novel coronavirus antigen and chicken IgY), sample pad, absorbent pad and PVC soleplate
(2) Buffer: 450ul each, buffer containing phosphate (ph6.5-8.0)
(3) Desiccant: a bag containing silica
Note: Do not mix the components of different kits

[STORAGE AND VALIDITY]

Store the test kit at 2°C-30°C, with a valid period of 12 months. Test strip should be used within 20 minutes once the foil pouch is opened. See the label for the

production date and service life.

[SAMPLE REQUIREMENT]

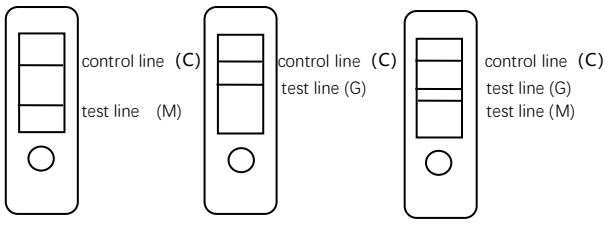
1. Apply to serum or EDTA, heparin and sodium citrate anticoagulant plasma/whole blood samples.
2. Immediately after specimen collection, shake up and down 5-10 times, and do not shake with force.
3. The samples should be detected immediately after collection. If they cannot be detected timely, they 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.

[TEST PROCEDURE]

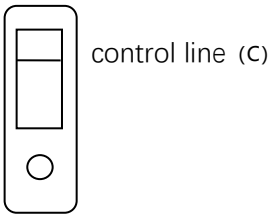
1. The test card, sample and sample diluent should be recovered to room temperature(15°C-30°C) before testing.
2. Open the aluminum foil bag of the test card, take out the test card and place it horizontally on the desktop.
3. Drain 65ul sample (serum, plasma, or whole blood) with a pipette and mix with the diluted solution, then add 65ul mixture into the sample hole of the test card.
4. Read the result within 15 minutes. And the results read after 18min are invalid.

[INTERPRETATION OF RESULT]

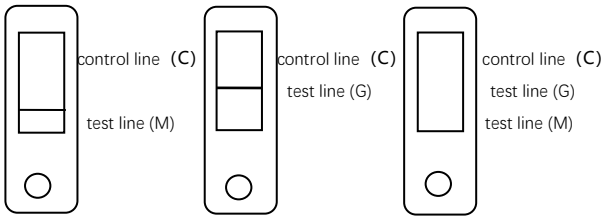
1. Positive results: Both the test line (G) and the control line (C) showed color bands, indicating that IgG antibody of the new coronavirus was positive; Both the test line (M) and the control line (C) showed color bands, and the new coronavirus IgM antibody was positive. The test line (M), (G) and control line (C) all showed color bands, and the new coronavirus 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 the novel coronavirus 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.



[PRODUCT PERFORMANCE]

1. Negative reference product compliance rate: the negative reference product compliance rate of the testing enterprise shall be 10/10.
2. Positive reference product compliance rate: the positive reference product compliance rate of the testing enterprise shall be 10/10.
3. Minimum test limit: reference products S1 of the minimum test limit of the testing enterprise shall be negative, and S2 and S3 shall be positive.
4. Repeatability: the detection rate of negative reference products in testing enterprises should be 100%, that of critical positive enterprises should be 95%, and that of medium positive enterprises should be 100%.
5. Analysis specificity

5.1 Cross reaction: the reagent has no cross reaction with 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.

5.2 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.
6. Clinical performance: In vitro diagnostic reagents were used to compare with the clinical diagnostic criteria of novel coronavirus pneumonia. The test results showed that the clinical sensitivity of the product was 88.12% (95%, CI: 83.12%, 90.26%), and the specificity was 99.23% (95%CI: 96.19%, 99.92%). In addition, 257 patients' homologous serum / plasma and whole blood samples (including 45 positive and 25 negative) were selected for comparative test. The results showed that with reference to the serum/plasma test results, the whole blood test results of the new coronavirus IgG antibody positive coincidence rate: 93.33% (95%ci: 87.21% ~ 95.12%), IgM antibody positive coincidence rate: 97.78% (95%ci: 90.12% ~ 98.99%), negative coincidence rate: 100.00% (95%ci: 96.12% ~ 98.0%), total consistency rate: 97.78% (95%ci: 93.12% ~ 98.05%). After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of epidemic situation. Further clinical data will be collected to confirm the clinical performance of the product after its release.

[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 highly hemolytic and lipid blood samples.
5. Only used for in vitro diagnostics. Please do not use it beyond the expiration date..
6. The damaged test strip or package cannot be used.

[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.

[BSAIC INFORMATION]

Registrant/Manufacturer Name: Wuhan Life Origin Biotech Joint Stock Co., Ltd
Address: Floor 1st, 2nd and 3nd, Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone 430206.
Telephone: 027-87196282
Aftersales Service: Wuhan Life Origin Biotech Joint Stock Co., Ltd
Telephone: 027-87926888
Manufacturing place: Floor 3st, Wuhan Hi-Tech Medical Device Park B11, No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone 430206.
Medical Device Manufacturer License Number: Hubei FDA 20100488
[Medical Devices Certificate Registration Number/Product Technical Requirement Number] Hubei FDA 20100488