Manual of SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) For Professional Use

FOR THE FAST QUALITATIVE ASSESSMENT OF SARS-CoV-2 IgM/IgG ANTIBODY IN HUMAN SERUM/PLASMA/WHOLE BLOOD.

Issued on 2020-03

SPECIFICATION

1 Test/Kit; 20 Tests/Kit

INTENDED USE

For in vitro qualitative detection of IgM and IgG antibodies in human serum, plasma or whole blood.

TEST PRINCIPLE

This kit adopts colloidal gold-immunochromatography assay (GICA). The test card contains 1) colloidal gold-labeled antigen and quality control antibody complex; 2) nitrocellulose membranes immobilized with two test lines (M line and G line) and one quality control line (C line).

When an appropriate amount of sample is added to the sample well of the test card, the sample will move forward along the test card under capillary action. If the sample contains an IgM/IgG antibody of SARS-CoV-2, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen, and the immune complex will be captured by the monoclonal anti-human IgM antibody or monoclonal IgG antibody immobilized on the nitrocellulose membrane to form a purple-red M line or G line, showing that the sample is positive for IgM or IgG antibody.

MATERIALS SUPPLIED

1	Disposable test card	5	Cotton swabs
2	Disposable plastic dropper	6	Desiccant
3	Sample diluent	7	Instruction manual
4	Peripheral blood collector		

STORAGE CONDITIONS AND VALIDITY

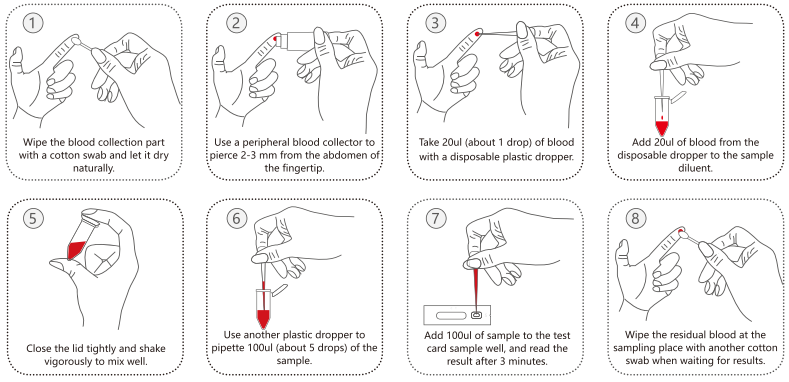
1. The original packaging should be stored in a dry place at 4-30°C and protected from light. The period of validity is 12 months.
2. After opening the inner package, the test card will become invalid due to moisture absorption, please use it within 1 hour.

APPLICABLE SPECIMEN

Applicable to human serum, plasma or whole blood samples, including peripheral blood, plasma prepared from clinically used anticoagulants (EDTA, heparin, sodium citrate), etc.

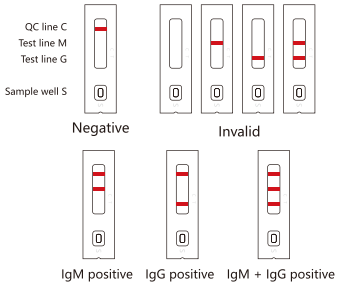
TEST PROCEDURE

Open the packing box, take out the inner package and let it equilibrate to room temperature. Please read the operation manual completely first, and use the kit within 1 hour after opening.



INTERPRETATION OF RESULTS

NEGATIVE:
If only the quality control line C appears, and the test lines M and G are not colored, it indicates that no antibody is detected, and the result is negative.
POSITIVE:
IgM positive: If both the quality control line C and the test line M appear colored, it indicates that the IgM antibody is detected, and the result is positive for IgM antibody.
IgG positive: If both the quality control line C and the test line G appear colored, it indicates that the IgG antibody is detected, and the result is positive for IgG antibody.
IgM and IgG positive: If the quality control line C and the test lines M and G all appear colored, it indicates that the IgM and IgG antibodies are detected, and the result is positive for both IgM and IgG antibodies.
INVALID: If the quality control line C is not observed, the test result is invalid regardless of whether there is a colored test line, and it should be tested again.



LIMITATIONS

1. This product is for qualitative assessment only.
2. The test results of this product are for reference only and are not the sole basis for diagnosis and treatment. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.
3. Due to the limitation of detection sensitivity, negative results may be caused by antibody concentrations lower than the analytical sensitivity of the product.

PERFORMANCE CHARACTERISTICS

The sensitivity, specificity and accuracy of SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) have passed the performance verification test of Nanjing Institute of Biomaterials and Medical Devices (Southeast University). Test results and conclusion are as follows:
Test results: Through the test results of using SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) to test on SARS-CoV-2 virus nucleic acid positive blood samples and negative blood samples, and blank diluent, it can be seen: The sensitivity of the reagent began to fail to detect IgG-positive strip after the S13HC antibody protein was diluted to 80 times (concentration: 71.4ng/mL); The detection accuracy of the reagent for positive samples was 100%, and the accuracy for negative samples was 95.8%; The test results of reagent on diluent were all negative, and the coincidence rate was 100%.
Conclusion: The sensitivity, specificity and accuracy of SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) are very high. SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold) is applicable to the detection and scientific research of SARS-CoV-2 virus antibodies in blood.

PRECAUTIONS

1. Operations should be performed in strict accordance with the instructions. Do not use expired or damaged products.
2. Take care to prevent virus infection when collecting samples. Please wear disposable gloves and masks when sampling, and wash your hands after testing.
3. The test card is capable of showing results in 3 minutes, and the whole process takes about 8 minutes.
4. When interpreting the result, if the test line M/G shows purple-red color, it is considered as a positive result. For positive results, it is recommended to use the colloidal gold retest cards attached for retesting. If the result is still positive, please contact local hospitals or disease control centers immediately.
5. If the quality control line C does not appear, please use the colloidal gold retest cards attached for retesting.
6. It takes a period of time for the antibody to be produced in the human body. It is recommended to retest 5-7 days after the first test.
7. This test card is for one-time use only. The used test cards and blood collection consumables should be properly discarded according to relevant regulations.

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