SARS-CoV-2 IgM/IgG Antibody Assay Kit (Colloidal Gold Method)

【Product Name】

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Colloidal Gold Method)

【Packing Specification】

Catalog No.	Package Size
HG01	25 T/kit
HG02	50 T/kit

【Intended Use】

This kit is used for the qualitative detection of specific IgM antibodies and IgG antibodies against novel coronavirus (SARS-CoV-2) in human specimens (serum, plasma, whole blood). Samples for testing shall be collected by professional medical personnel.

【Introduction】

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. The SARS-COV-2 specific IgM antibody starts to be detected after 3-5 days from onset. While The SARS-COV-2 specific IgG antibody can be detected with 1-3 weeks after onset. The seroconversion rate and the antibody levels increased rapidly during the first two weeks, some patients with negative nucleic acid could screen out through antibody testing. Combining PCR test and antibody test significantly raise the sensitivity for detecting suspected case. The antibody detection is an important indicator of dynamic detection of disease diagnosis and treatment.

【Test Principle】

This kit applies the principle of lateral flow chromatographic immunoassay and uses capture method to detect specific IgM and IgG antibodies against novel coronavirus in human specimens. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and chicken IgY monoclonal antibody gold conjugates , 2) a nitrocellulose membrane strip containing anti human IgG, M band is coated with anti-human IgM, and the C band is pre-coated with goat anti-chicken polyclonal antibody.

When the specimen is dispensed into the sample well, if the specimen contains novel coronavirus IgM antibodies and the concentration is equal to or higher than the limit of detection (LOD), the antibody binds to the labeled antigen and is captured by the secondary antibody to form a red IgM test line. In this case, the result is positive for the novel coronavirus IgM antibody. When the specimen contains novel coronavirus IgG antibodies and the concentration is equal to or higher than the LOD, the antibody binds to the labeled antigen and is captured by the secondary antibody to form a red IgG test line. In this case, the result is positive for the novel coronavirus IgG antibody. Conversely, if neither IgM test line nor IgG test line is visible, the result is negative. Under normal test conditions, the quality control line (C) should be clearly visible to indicate a valid test.

【Main Components】

The kit includes a test card, dropper with diluent (optional) a dropper (optional), dilution device (optional).

The test card consists of a novel coronavirus (SARS-CoV-2) IgM/IgG antibody test strip and a plastic cassette. The test strip is composed of nitrocellulose membrane, colloidal gold label pad, sample pad, absorbent paper and bottom plate.

【Storage and Validity】

Stored at 4-30℃ for 12 months, protecting from direct sun light and humidity. Do not freeze the kit. Use the kit immediately after opening the sealed aluminum foil bag.

【Specimen Requirements】

1. Sample type: serum, plasma and whole blood.

2. Separate serum or plasma and test it as soon as possible after sample collection to avoid hemolysis. If it cannot be tested in time, please store at 2-8℃ for no more than 3 days. If over 3 days, please store the sample frozen at -20℃. Completely thaw, warm and mix the frozen samples well before test. Avoid repeated freeze-thaw cycles.

【Application Procedures】

Please read the instruction manual carefully before use the kit. The kit and sample should be rewarmed to room temperature of 20-30℃ before test.

1. Open the aluminum foil bag, take out the test card and label the specimen and patient information on it.

2. Sampling method

2.1. Method I

Using the optional quantitative dilution device, the sample end is first immersed in the serum, plasma, whole blood, the sample will automatically siphon to the top（5 μL）. Insert the sample-filled suction tube into the dilution tube containing the diluent, mix it upside down, then discard the first drop, and then add 2 drops to the sampling hole.

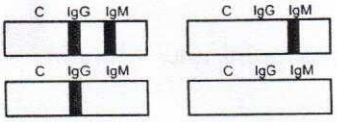
2.2. Method II

Use pipette or burette（optional） add 5 μL serum, plasma or whole blood vertically to the sample well of the test card, and then add approximately 2 drops (about 80μL) of sample dilution buffer to the sample well of the test card.

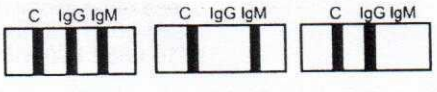
3. The result should be read strictly within a time limit of 10-15 minutes, and the results read after 15 minutes are invalid.

【Interpretation of Results】

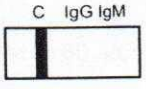
1. **Invalid**: When the quality control line (C) is not visible, the test is invalid. It is recommended to repeat the test with a new test card in this case. Pay special attention to whether the amount of sample is sufficient.



2. **Positive**: When the quality control line (C) is visible and any one of the detection lines is visible.



3. **Negative**: Only the quality control line (C) is visible.



【Assay performance】

1. **Cross-reactivity**: Cross-reactivity for this assay kit was evaluated with positive samples of parainfluenza virus antibodies, influenza A virus antibodies, influenza B virus antibodies, Chlamydia pneumonia antibodies, Mycoplasma pneumonia antibodies, adenovirus antibodies and respiratory syncytial virus antibodies, the test results for these positive samples are negative, no cross-reactive occurs.

2. **Class specificity**: IgM is positive and IgG is negative when tested with PA, IgM is negative and IgG is positive when tested with PB; when tested with PA + PB, IgM and IgG are positive and single test result is consistent with the mixed test result. There is no cross-reaction and competitive-reaction between IgM and IgG antibodies.

3. **Clinical performance**: there are 120 samples including 75 positive samples and 45 negative samples evaluated in this study. For IgG antibody test, the clinical sensitivity is 84.0%, 95% CI: (74.08%, 90.60%); specificity is 93.33%, 95% CI: (82.14%, 97.71%); accuracy is 87.5%, 95% CI: (80.40%, 92.28%). For IgM antibody test, the clinical sensitivity is 97.33%, 95% CI: (90.79%, 99.27%); specificity is 93.33%, 95% CI: (82.14%, 97.71%); accuracy is 95.83%, 95% CI: (90.62%, 98.21%). For the kit, clinical sensitivity is 98.67%, 95% CI: (92.83%, 99.76%); specificity is 91.11%, 95% CI: (79.27%, 96.49%); accuracy is 95.83%, 95% CI: (90.62%, 98.21%).

【Limitations of Detection Methods】

1. This kit is only used for testing human serum, plasma and whole blood samples.

2. The accuracy of the test depends on the sample collection process, which is affected by improper sample storage, hemolysis or repeated freeze-thaw.

3. This kit is used for the qualitative detection of antibodies against novel coronavirus (SARS-CoV-2) in human specimens (serum, plasma, whole blood). Not accurately determine the antibody content in the sample.

4. The result of this reagent is only for clinical reference, not as 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 and treatment reactions.

5. Limited by the methodology of antibody detection reagents. the negative results should be rechecked and confirmed by nucleic acid detection or virus culture.

6. Analysis of the possibility of false negative results:

- Unreasonable sample collection, transportation and handling, low virus titer in the samples may lead to false negative results;
- The variation of virus genes may lead to the change of antibody determinant, which may result in false negative results.

7. This assay kit is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

【Product Performance Indicator】

1. Positive reference coincidence rate: test 3 samples of internal positive reference (P1 to P3) with the test card, and the results should all be positive.

2. Negative reference coincidence rate: test 6 samples of internal negative reference (N1 to N6) with the test card, and the results should be all negative.

3. Limit of Detection: IgM-0.25 μg / mL; IgG-0.23 μg / mL.

4. Repeatability: Test 1 sample of enterprise internal reference (J) for 10 times repeatedly, and the results should be positive and consistent.

【Warnings and Precautions】

1. This reagent is for in-vitro diagnostic use only.

2. Do not use the test cards with damaged aluminum foil bag, unclear marks, or expired test card.

3. The quality control line (C) is the marker of reliable results. If the quality control line (C) is invisible, the test is invalid. The specimen should be retested with a new test card in this case.

4. This kit is disposable and should be treated as biohazard waste after use.

5. Avoid vertical air flow, which may affect the result of the reagent.

6. This product is strictly for medical professional use only and not intended for personal use. The administration of the test and interpretation of results should be done by a trained health professional.

【Explanations on Symbols】 CE

Symbol	Explanation
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	LOT CODE
	CONSULT INSTRUCTIONS FOR USE
	PRODUCTION DATE
	USE-BY DATE
	TEMPERATURE LIMIT
	MANUFACTURER
CE	EUROPEAN CONFORMITY
EC REP	AUTHORIZED REPRESENTATIVE IN
REF	CATALOGUE NUMBER

【References】

1.Guidelines for Diagnosis and Treatment of COVID-19 (the Seventh Edition), the National Health and Medical Commission.

【Manufacturer Information】

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