Diagnostic Kit (Colloidal Gold）for IgG/IgM Antibody to SARS-CoV-2 Package Insert
(For in vitro diagnostic use only)

INTENDED USE

The Diagnostic Kit （Colloidal Gold ）for IgG/IgM Antibody to SARS-COV-2 is a rapid immunoassay for the qualitative detection of antibodies (IgG and IgM) to SARS-COV-2 virus in Whole Blood/Serum/Plasma.

SUMMARY

Coronaviruses belong to the Nidovirales Coronaviridae and Coronavirus A large class of viruses found widely in nature. The 5 'end of the viral group has A methylated cap structure, and the 3' end has A poly (A) tail, the genome was 27-32kb long. It is the largest known RNA virus with the largest genome. Coronaviruses are divided into three genera: α,β, γ.α,β only the mammal pathogenic, γ is mainly lead to infections of the birds. CoV was also demonstrated to be transmitted mainly through direct contact with secretions or through aerosols and droplets, and it has been shown to be transmitted via the fecal-oral route. Coronaviruses are associated with a variety of diseases in humans and animals, causing diseases of the respiratory, digestive and nervous systems in humans and animals. So far, seven human coronavirus (HCoV) viruses have caused respiratory diseases in humans: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-COV-2. Globally, 10% to 30% of upper respiratory tract infections are caused by the four classes of coronavirus: HCoV-229E, HCoV-OC43, HCoV-NL63 and HCoV-HKU1.

SARS-COV-2 was found for a case of viral pneumonia in Wuhan in 2019, is a kind of before a new type of coronavirus has not been found in human. SARS-COV-2 belongs to the β coronavirus, which is enveloped, and the particles are round or elliptic, often pleomorphic, with a diameter of 60~140nm, and its genetic characteristics are significantly different from those of SARS-CoV and MERS-CoV. The clinical manifestations are fever, fatigue and other systemic symptoms, accompanied by dry cough, dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multi- organ failure, severe acid-base metabolic disorder, and even life-threatening. SARS-COV-2 transmission has been identified primarily through respiratory droplets (sneezing, coughing, etc.) and contact transmission (nostril picking, eye rubbing, etc.).

The virus is sensitive to ultraviolet light and heat and can be effectively inactivated by 56℃ for 30 minutes or lipid solvents such as ethyl ether, 75% ethanol, chlorine-containing disinfectant, peroxyacetic acid and chloroform.

PRINCIPLE

The Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood. This test consists of two components, an IgG component and an IgM component. In the Test region, anti- human IgM and IgG is coated. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgM or IgG in test line region. If the specimen contains IgM or IgG antibodies to SARS-CoV-2, a colored line will appear in test line region.

Therefore, if the specimen contains SARS-CoV-2 IgM antibodies, a colored line will appear in test line region M. If the specimen contains SARS-CoV-2 IgG antibodies, a colored line will appear in test line region G. If the specimen does not contain SARS-CoV-2 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid, and the specimen must be retested with another device.

KIT COMPONENTS

- Individually packed test devices 5 tests/kit, 25 tests/kit or 1/tests kit
- Sample diluents 1vail/kit
- Disposable pipettes 1/ kit or 25 /kit
- Package insert 1copy/kit

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer
- Centrifuge

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. The kit can be stored at room temperature (2°C -30°C, do not freeze) for 12 months from the date of manufacture. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before use and should be used within 1 hour after opening the pouch (within the temperature of 2°C~30°C and humidity less than 80%); The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND STORAGE

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

- **Whole Blood**

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

- **Plasma**

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture. Separate the plasma by centrifugation. Carefully withdraw the plasma into new pre-labeled tube.

- **Serum**

Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by veinpuncture, Allow the blood to clot. Separate the serum by centrifugation. Carefully withdraw the serum into a new pre-labeled tube. Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately. Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on results interpretation.

ASSAY PROCEDURE

Before any test, the package Insert must be read thoroughly. Bring the specimen and test components to room temperature Mix the specimen well prior to assay once thawed.

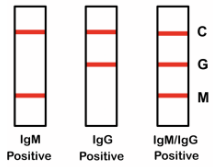
- **Visual inspection method:**

Step 1: Place the test device on a clean, flat surface.

Step 2: Fill the capillary tube and transfer approximately 10 µL (or 1 drop) of whole blood specimen to the specimen well of the test device, then add 2 drops of Sample Diluent (about 60µL ~100µL) immediately into the sample well to assist the sample detection.

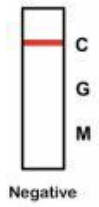
Step 3: The test results should be read in 10-15 minutes, and the results read after 15 minutes are invalid.

INTERPRETATION OF RESULTS

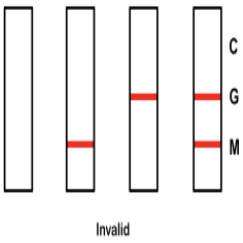


Positive:
The colored line in the control line region (C) appears and at least a colored line appears in test line region G (G) or test line region M (M). The appearance of G test line indicates the presence of SARS-CoV-2 specific IgG antibodies. The appearance of M test line indicates the presence of SARS-CoV-2 specific IgM antibodies. And if both G and M line appear, it indicates that the presence of both SARS-CoV-2 specific IgG and IgM antibodies

***NOTE:** The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of SARS-CoV-2 antibodies in the specimen. Therefore, any shade of color in the test line region(s) (G and M) should be considered positive.



Negative:
The colored line in the control line region (C) appears. No line appears in test line regions G and M (G and M).



Invalid:
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

WARNINGS AND PRECAUTIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to nCoV-19. Failure to follow the procedure may give inaccurate results.
2. The sample should be tested in the laboratory with certain conditions. All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.
3. Be careful to prevent the product from getting wet, and do not open the aluminum bag before it is ready for testing; If the aluminum foil bag is damaged or the test card is damp, it cannot be used.
4. Please use it within the validity period.
5. Do not use cloudy pollution samples for testing.

6. Do not dilute the sample for testing, otherwise inaccurate results may beobtained.

7. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.

8. The interpretation of inspection methods and results shall be strictly in accordance with this manual.

9. This kit is limited to qualitative detection of SARS-CoV-2 antibodies whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.

10. The kit will produce negative results under the following conditions: when the titer of the SARS-CoV-2 antibody in the specimen is below the minimum detection limit of the kit, or when the SARS-CoV-2 antibody is not present at the timeof specimen collection.

11. Specimen containing higher titers of heterophobic antibodies or rheumatoid factors may affect the expected results.

LIMITATION

1. The SARS-CoV-2 IgG/IgM Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antibodies in Whole Blood.
2. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
3. The SARS-CoV-2 IgG/IgM Test cannot be used to differentiate if the infection is primary or secondary. No information of nCoV-19 serotypes can be provided with this test.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative or non-reactive test result does not preclude the possibility of exposure to or infection with SARS-CoV-2 virus at anytime.
5. Serological IgM antibody testing is of limited reference value in patients with impaired immune function or receiving immunosuppressive therapy.
6. The positive test results of people who have recently received blood transfusion or other blood products in recently should be carefully analyzed.
7. All ingredients in the kit have been tested in the same batch. It is not recommended to mix with reagents with different batch.
8. If the symptom persists, while the result from SARS-CoV-2 IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.

REFERENCES

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SYMBOLS

	Consult instruction for use		Test per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number	REF	#Catalog
	Do not use if package id damaged				

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Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2
Clinical Report Summary

- **Comparative analysis of test reagent results with nucleic acid test results.**
- **The detection results of test reagent (IgG/IgM) and clinical diagnostic results are shown in the following table:**

		Clinical Diagnostic Result		
		Confirmed Diagnostic	Exclusion	Total
Test Reagent Results	Positive (+)	186	8	194
	Negative (-)	16	372	388
Total Number		202	380	582

Sensitivity: %92,08; (%95 Cl: %87,52-%95.07)
Specificity: %97,89; (%95 Cl: %95,90-%98,93)
Total clinical coincidence rate: %95,88 (%95 Cl: %93,94-%97,21)

- **Comparative analysis of test reagent results with nucleic acid test results.**
- **The detection results of test reagent (IgG/IgM) and the nucleic acid test results were shown in the following table:**

		Nucleic Acid Test Results		
		Positive (+)	Negative (-)	Total
Test Reagent Results	Positive (+)	116	78	194
	Negative (-)	10	378	388
Total Number		126	456	582

Positive Coincidence Rate: %92.06; (%95 Cl: %86.01-%95,63)
Negative Coincidence Rate: %82,89; (%95 Cl: %79,17-%86.07)
Total Coincidence Rate: %84,88; (%95 Cl: %81,74-%87.56)

- **Analysis of results of continuous samples collected from the same patient at different time points.**
- **Statistical analysis of test results were shown in the following table:**

Test Reagent Results	Number Of Cases	Percentage
Earlier than the nucleic acid test results	3	%15
Same as the nucleic acid test results	14	%70
Later than the nucleic acid	3	%15

- **The above results showed that there was no statistically significant difference between the detection reagent and the clinical diagnostic results.**