Coronavirus Disease 2019 (COVID-19) IgM/IgG Rapid Test

(Colloidal Gold Assay)

Instructions For Use

【Intended Use】

The COVID-19 IgM/IgG Rapid Test (Colloidal Gold assay) is for detection of IgM and IgG antibodies against SARS-CoV-2 from human clinical specimen (serum, plasma or whole blood).

【Summary】

Coronavirus (CoV) belongs to the Coronoaviridae family and is divided into three types: α, β and γ. Alpha and beta are only pathogenic to mammals and gamma mainly causes birds infection. To date there are four types of alpha coronavirus (HCoV-229E, HCoV-NL63, HCoV-OC43 and HCoV-HKU1) and three types of beta coronavirus (SARS-CoV, MERS-CoV and SARS-CoV-2) that cause human respiratory diseases. SARS-CoV-2 was first discovered in Wuhan, China during an unexplained viral pneumonia outbreak in late 2019. Human-to-human transmission is through direct contact, aerosols/droplets, or possibly the fecal-oral route. The clinical manifestations of COVID-19, the disease caused by SARS-CoV-2, include fever, cough and fatigue. Severe cases can develop into acute respiratory distress syndrome (ARDS), septic shock, kidney or multiple organ failure, and even life-threatening [1-3].

【Test Principle】

The Mokobio Colloidal Gold COVID-19 IgM/IgG test employs an immunochromatography assay, in which antigen is labeled with colloidal gold. The antigen is a fusion protein, comprised of the SARS-CoV-2 Spike (S) antigen at the N-terminus and the mouse IgG Fc fragment at the C-terminus. Three capture lines are used, which are coated with mouse anti-human IgM monoclonal antibody (M line, M), mouse anti-human IgG monoclonal antibody (G line, G), and anti-mouse IgG Fc fragment antibody (control line, C). When patient sample is added to the sample well, SARS-CoV-2 IgM or IgG binds to the N-terminus of the fusion protein forming antigen-antibody complexes. During the lateral flow chromatography, these antigen-antibody complexes, if there is any, are captured by anti-human IgM or IgG antibodies immobilized on the membrane, forming a purple-red M line and/or a purple-red G line. showing that the respective SARS-CoV2 antibody is present. The test cassette also contains a quality control line, which should appear regardless of the M and G line results.

【Kit Contents】

One test kit contains:

20 Test Cassettes | 1 Buffer Solution Bottle (5 mL) | 1 Package Insert

One test cassette contains:

- Colloidal gold-labeled recombinant SARS-CoV-2 antigen fused with mouse IgG Fc fragment
- Mouse anti-human IgM monoclonal antibody
- Mouse anti-human IgG monoclonal antibody
- Anti-mouse IgG Fc fragment antibody

Materials not provided but required:

Lancet | Capillary Samplers | Alcohol wipes | Gloves | Timer |

【Warnings and Precautions】

• For in vitro diagnosis only.
• This product is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing
• The test cassette should be used within one hour after opening the sealed pouch. Use immediately when the ambient humidity is greater than 60%.
• Do not freeze test cassette or buffer solution.
• Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens [4].
• Wear protective gloves, clothing, and eyewear.
• Wash hands thoroughly after handling specimens.
• Do not use test cassette, buffer solution, or any other kit components beyond the expiration date indicated.
• Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
• Dispose of all used or damaged test cassettes, capillary samplers, or other kit component as biohazardous materials.

【Storage】

The reagent should be stored in the dark at room temperature (15-30°C) and has a shelf-life of 12 months. Do not freeze.

【Sample Requirement】

• Suitable for human serum, plasma, or whole blood (venous or capillary) samples including samples prepared by commonly-used anticoagulants (EDTA, heparin, sodium citrate).

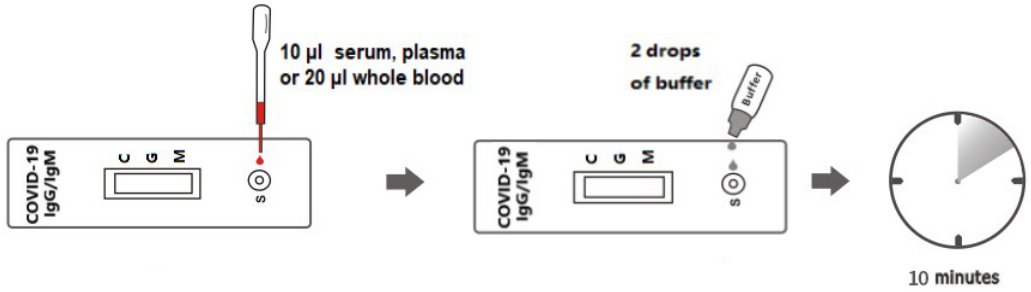
• For best performance fresh samples should be collected and tested immediately.

• Serum and plasma samples can be stored at 2-8°C for 7 days. If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze/thaw cycles.
• Anticoagulated whole blood samples can be stored at 2-8°C for 5 days.
• Before testing, samples stored in refrigerated or frozen storage should be slowly recovered to room temperature (15-30° C) and stirred. When particulates are clearly visible in the sample, the precipitate should be removed by centrifugation before testing.
• Do not use samples with severe hemolysis, lipemia, or jaundice.

【Test Procedure】

Do not open pouch until ready to use.
Prep necessary materials: Test cassette | Buffer solution | Capillary Sampler
Label Test cassette with patient ID.
1. Remove the cassette from its protective pouch, lay it on a dry and clean flat surface, and label the cassette with patient or specimen number.

2. Use a micropipette or a dropper to take 10 µl of serum, plasma or 20 µl whole blood sample, directly add into the well, and then add 2 drops (about 50 µl) assay buffer into the well. Start the timer.
3. Leave the cassette at room temperature and read the results within 10 minutes. **Test result is invalid after 20 minutes**.



【Test Method Limitations】

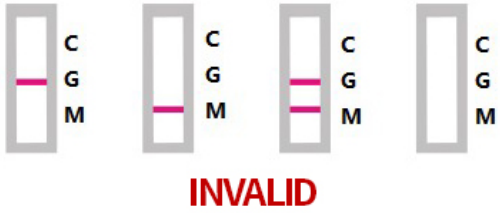
• This product can only be used to detect SARS-CoV-2 IgM/IgG antibody in human serum, plasma or whole blood (venous or capillary). It cannot be used with other body fluids or secretions.
• This product is only for qualitative testing and the specific content of each indicator must be determined using other quantitative methodologies.
• Negative results may be caused by low concentrations of SARS-CoV-2 IgM/IgG antibody in the sample and therefore cannot completely rule out the possibility of infection.
• The results of this test are for clinical reference only and should not serve as the only basis for diagnosis. Results should be used in combination with clinical symptoms and other testing methods.
• Test results can be affected by temperature and humidity.

【Display of Results/Expected Values】

Negative: If only a purple-red line appears at the control line (C), G and M lines are not detected in the test region, it means that no SARS-CoV2 IgG/IgM has been detected and the result is negative.
Positive:
1. If both control line C and test M line appear, it means that SARS-CoV2 IgM antibody has been detected and the result is positive for IgM antibody.
2. If both control line C and test line G line appear, it means that SARS-CoV2 IgG antibody has been detected and the result is positive for IgG antibody.
3. If control line and both test lines M and G line appear, it means that SARS-CoV2 IgM and IgG antibodies have been detected and the result is positive for both IgM and IgG antibodies.

【Internal Quality Control】

The control line C serves as a built-in quality control for assay validity. If quality control line C does not appear, it indicates that the test result is invalid, and the test should be repeated.



【Performance Characteristics】

1. Sensitivity and specificity:

The clinical performance of the Mokobio SARS-CoV-2 IgM/IgG Rapid Test (Colloidal Gold Assay) had been evaluated. A total of 185 serum specimens were collected from 68 patients with known SARS-CoV-2 infection (confirmed by RT-PCR results) and 117 non-infected patients (excluded by RT-PCR results and clinical symptoms). The overall assay sensitivity and specificity are 85.29% (95% CI: 74.61%-92.72%) and 97.44% (95% CI: 92.69%-99.47%), respectively.

All sites		RT-PCR Results			
		Positive	Negative	Total	
MOKOBIO Device Results	Positive	58 [a]	3	61	Sensitivity 85.29% 95% CI (74.61%-92.72%)
	Negative	10	114	124	Specificity 97.44% 95% CI (92.69%-99.47%)
	Total	68	117	185	

a. Of 58 samples with positive test results, 39 samples are IgM & IgG double positive, 14 samples are IgM positive only, 5 samples are IgG positive only.

2. Cross-reactivity:

No cross-activity was observed when testing negative samples with high population prevalence of antibody against Influenza A, Influenza B, RSV, HBV due to vaccination and/or natural infection.

3. Class specificity:

Class Specificity has been examined using purified human IgM or IgG mixture. No cross-reactivities between IgM and IgG were observed.

【Notes for Clinical Use in United States】

Please note the following information and include it in test reports

• This test has not been reviewed by the FDA.

• Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

• Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2

infection or to inform infection status.
• Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
• Not for the screening of donated blood.

【References】

[1] Nanshan Chen*, Min Zhou*, Xuan Dong*, et al., Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. Lancet, 2020, 395(10223):507-513.
[2] Chaolin Huang, Yeming Wang, Xingwang Li, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet.2020,395(10223),497-506.
[3] Jasper Fuk-Woo Chan, Shuofeng Yuan, Kin-Hang Kok, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. Lancet. 2020, 395(10223), 514-523.
[4] Chao, E.L.; Henshaw, J.L. Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. OSHA. 3186-06R, 2003.

【Manufacturer】

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