SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay

Instructions for Use

【Intended Use】

The Mokobio SARS-CoV-2 IgM & IgG Quantum Dot immunoassay is for detection of IgM and IgG antibodies against SARS-CoV-2 from human clinical specimen (serum or plasma).

【Summary】

Coronavirus (CoV) belongs to the Cronoaviridae 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 coronaviruse (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 SARS-CoV-2 IgM & IgG Quantum Dot test employs an immunofluorescent assay, in which antigen is labeled with quantum dots (QDs) fluorescent microsphere. 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 (Test line 1, T1), mouse anti-human IgG monoclonal antibody (Test line 2, T2), 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 the anti-human IgM/IgG monoclonal antibodies, and their relative abundance can be quantified by the fluorescence signal at the corresponding test line(s). The C-line antibody captures the excess QD-labeled fusion protein through the mouse IgG Fc fragment, serving as an internal control. The fluorescence intensity of T1 or T2 directly reflects the relative content of SARS-CoV-2 IgM or IgG antibody in the specimen.

【Kit Contents】

One test kit contains:

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

One test cassette contains:

- Quantum Dots-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 | Quantum Dots Immunofluorescence Analyzer

【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.

【Compatible Instruments】

This product is compatible with the Quantum Dots Immunofluorescence Analyzers manufactured by Mei Ning Kang Cheng China Biotechnology R&D Center INC. (Model: Mokosensor-Q240 and Mokosensor-Q100).

【Sample Requirement】

• Suitable for human serum and plasma 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】

Prepare necessary materials including Test Cassette, Buffer Solution and Capillary Sampler before testing.

1. Restore test specimen to room temperature.
2. Tear open pouch to retrieve Test Cassette; label each test cassette with a patient ID.
3. Dispense sample specimen into Test Cassette.

Using a Capillary Sampler or pipette, add 20μL of serum or plasma sample into the sample well of Test Cassette.

4. Dispense buffer solution into Test Cassette.

Remove the cap of the Buffer Solution bottle and dispense 2-3 drops (~100μL) into the Test Cassette sample well.

5. Incubate the Test Cassette at room temperature for 10 min on a level surface.
6. Read test result by Quantum Dots Immunofluorescence Analyzer.

Insert the Test Cassette into a Mokosensor Q100 or Q240 Quantum Dots Immunofluorescence Analyzer (manufactured by Mei Ning Kang Cheng China Biotechnology R&D Center INC.) to obtain the test result. Test Cassette is recommended to be analyzed within 10 min after incubation, but the quantum dots fluorescence signal is stable for > 1 week if Test Cassette is kept out of light.

7. A product information card (IC), if supplied, contains batch information, calibration, etc. Hold the IC card at the sensor zone on the back of the instrument to retrieve the stored information.

【Test Method Limitations】

• This product can only be used to detect SARS-CoV-2 IgM/IgG antibody in human serum, plasma. Test performance has not been validated with 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】

The test result for SARS-CoV-2 IgM/IgG is displayed as “positive” or “negative”, along with a relative fluorescence intensity value normalized to the control line. Four result combinations are possible:

Negative: both SARS-CoV-2 IgM and SARS-CoV-2 IgG are negative.

IgM Positive: SARS-CoV-2 IgM is positive and SARS-CoV-2 IgG is negative.

IgG Positive: SARS-CoV-2 IgM is negative and SARS-CoV-2 IgG is positive.

Double Positive: both SARS-CoV-2 IgM and SARS-CoV-2 IgG are positive.

【Internal Quality Control】

Each Test Cassette has a built-in Control line to monitor procedural mistake and reagent defect. If the fluorescence intensity value of the control line is below a certain threshold a "warning" symbol will be prompted. The test result is invalid, and a new test must be performed. If the problem persists, please contact your local vendor or Mokobio for technical support.

【Performance Characteristics】

1. Sensitivity and specificity:

The clinical performance of the Mokobio SARS-CoV-2 IgM/IgG quantum dot immunoassay had been evaluated. A total of 262 serum specimens were collected from 105 patients with known SARS-CoV-2 infection (confirmed by RT-PCR results) and 157 non-infected patients (excluded by RT-PCR results and clinical symptoms). The overall assay sensitivity and specificity are 89.52% (95% CI: 82.03%-94.65%) and 99.36% (95% CI: 96.50%-99.98%), respectively.

All sites		RT-PCR Results			
		Positive	Negative	Total	
MOKOBIO Device Results	Positive	94 (1)	1	95	Sensitivity 89.52% 95% CI (82.03%-94.65%)
	Negative	11	156	167	Specificity 99.36% 95% CI (96.50%-99.98%)
	Total	105	157	262	

(1) Of 94 samples with positive test results, 67 samples are IgM & IgG double positive, 18 samples are IgM positive only, 9 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-SPARS-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 [J]. The 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 [J]. The 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 [J]. The 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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