

## Detection of Nucleic Acid and Antibody of New Coronavirus

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The pandemic of Coronavirus Disease 2019 (COVID-19) has been taking lives worldwide. The detection of pathogens is of great significance to control the development of epidemic situation and save the lives of patients. Nucleic acid detection based on reverse transcription and real-time polymerase chain reaction (RT-PCR) is the main detection method at present, which is of great significance to epidemic control, but the positive detection rate is low due to many factors. Detection of COVID-19 antibody serum is simple and easy in theory, and shows high sensitivity and specificity. It can ensure the reliable detection results of COVID-19 by combining the nucleic acid detection and antibody detection.

Currently, COVID-19 has spread too many countries around the world. The infected pathogen was a new type of coronavirus confirmed by pathogenic gene sequencing, and it was similar to previous outbreaks of human coronavirus infection, the rapid development and spread of COVID-19 has become a public health emergency of international concern [1]. Hence, rapid, simple, sensitive and accurate detection methods are urgently needed to diagnose the COVID-19 to prevent the spread of the virus and ensure that patients get treatment in time.

Nowadays, the main methods of diagnosis COVID-19 include RT-PCR detection of virus nucleic acid, CT of chest and some hematological parameters in clinical. A number of research institutes have developed laboratory test kits to detect COVID-19 specimens of patients. Detection of viral nucleic acid by RT-PCR has become the standard method for diagnosis COVID-19 [2]. However, these RT-PCR detection kits have many limitations including

1. The detection cycle is long and the operation is complicated, and it takes at least 2-3 hours to produce results.
2. Testing process requires certified laboratories, expensive equipment and trained technicians to operate.
3. There was a certain number of false negatives in the test results. These limitations make the RT-PCR detection method not fully applicable to the rapid and simple diagnosis of COVID-19.

It is theoretically rapid, simple and highly sensitive to detect virus-specific antibodies in the blood of COVID-19 patients. Generally, it is believed that IgM is the first defensive line against viral infection before producing adaptive IgG with high-affinity response that is important for long-term immune and immune memory [3]. It was reported that IgM could be detected in the patient's blood after 3-6 days and IgG after 8 days of infection with SARS [4,5]. Since COVID-19

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are homologous to viruses that cause MERS and SARS, we hypothesized that their antibody production processes are similar, and it can serve as markers of infection to detect the IgG and IgM antibodies against COVID-19. Moreover, detection of IgM antibodies often indicates exposure to COVID-19 recently, while IgG antibodies indicates exposure to the virus some time ago. Therefore, we believe that both IgM and IgG can provide information about the time process of virus infection. Rapid detection of IgM and IgG antibodies is of great value in the diagnosis and treatment of COVID-19 diseases.

Recently, Chu et al proposed IgG-IgM combination antibody tests for COVID-19 infection to study different stages of infection. A total of 525 cases were tested including 397 infected patients with positive COVID-19 and 128 patients with negative non-COVID-19 infections. As a result, 352 of the 397 blood samples from COVID-19 infected patients were tested positive, with a sensitivity of 88.66%. And 12 of the blood samples from 128 patients with non-COVID-19 infection tested positive, with a specificity of 90.63%. Meanwhile, 64.48% (256 of 397) positive patients were found to have both IgM and IgG antibodies. For a simpler procedure, they also tested the performance between the IgG-IgM combined antibody kit and peripheral blood. The results showed a high consistency of detection between samples in fingertip blood, serum and venous blood plasma. IgG-IgM combination antibody detection kit can be used as an immediate test (POCT). People can be examined by fingertip blood collection [6].

This novel and rapid IgG-IgM combination antibody detection has several advantages. Compared with RT-PCR detection, it saves time and does not require special equipment, and is easy to operate and requires little training. It can be done at the bed, in any clinic or laboratory, airport or railway station. Another potential application is screening asymptomatic COVID-19 carriers that are reported to be able to transmit COVID-19 viruses [7,8]. Because the test can detect

both IgM and IgG, it can be used for early diagnosis and monitoring during treatment. COVID-19 infection begins in the lungs and not in the upper respiratory tract [9], therefore, sampling with a laryngeal swab or sputum may not detect the virus at early stage of infection. It is a possible explanation for the higher false negative in nucleic acid PT-PCR tests. Nevertheless, its sampling will not have any effect on the IgM and IgG test results.

False positive and negative results were also present in IgG-IgM combination antibody tests. Firstly, the reason for false negative may be due to low antibody concentration. When the IgM and IgG levels are below the detection limit of this rapid test, the test results will be negative. Secondly, differences in the individual production immune response antibodies may be one of the reasons for false negative outcomes in COVID-19 patients. At last, the IgM antibody will decrease and disappear after 2 weeks. In some cases, it is difficult to know exactly when or how long the patient was infected. Therefore, the IgM level is likely to be lower than its peak, so it cannot be detected effectively [10]. So, we encourage more research and development of IgG-IgM combined antibody detection in COVID-19 patients to improve their diagnostic sensitivity and specificity.

Of course, antibody testing does not confirm the presence of the virus and can only provide evidence of recent infections, but it provides doctors with important immunological evidence that can be combined with other test methods to make the correct diagnosis and start treating patients. Furthermore, detecting antibody cannot compare the change of antibodies levels at different stages of COVID-19 infection. We believe, however, that combining nucleic acid RT-PCR with IgM-IgG antibody can provide a more accurate diagnosis of COVID-19 infection.

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