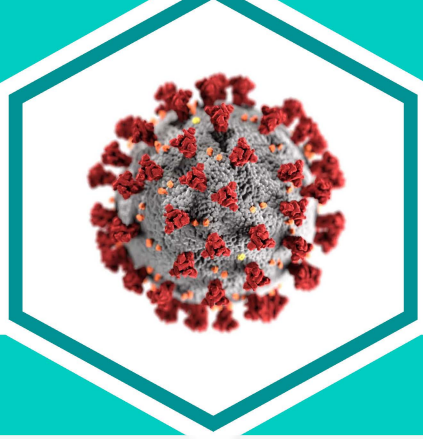
LABTECH™
DIAGNOSTICS
AT THE FOREFRONT OF LABORATORY MEDICINE

SARS-CoV-2 IgM/IgG



TEST ID: 39000
TUBE TYPE: SST
SAMPLE TYPE: SERUM

WHY DO WE NEED ANTIBODY TESTS FOR COVID-19?

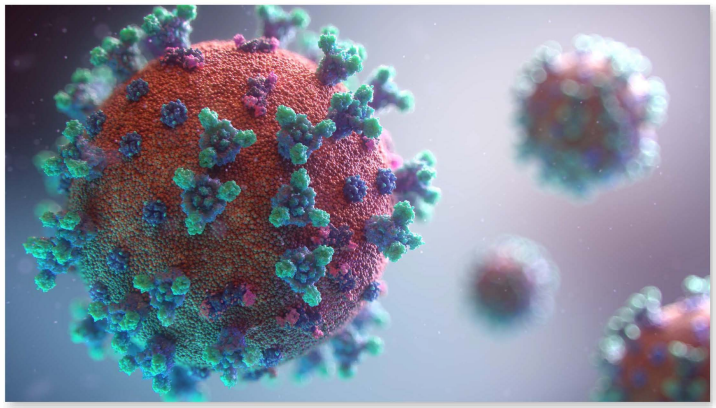
Diagnosing viral infections currently relies on two major methodologies: Reverse Transcription Quantitative Polymerase Chain Reaction (RT-qPCR) and serological immunoassays that detect virus-specific antibodies (IgM and IgG) or antigens.

Although, RT-qPCR is a highly sensitive test for SARS-CoV-2 (the virus that causes COVID-19) it has its limitations. RT-qPCR requires high-quality nasopharyngeal swabs containing sufficient amounts of viral RNA. This can be a challenge because the amount of viral RNA not only varies tremendously between patients, it can also vary within the same patient depending on the timing of the test and the start of the infection and/or the onset of symptoms. In addition, nasopharyngeal swabs are unpleasant to the patient, and the sampling techniques vary significantly from nurse to nurse. Without sufficient viral RNA RT-qPCR can return a false negative test result. RT-qPCR also requires highly trained personnel to perform complex RNA extraction steps and PCR.

Normally, this would not be a problem when testing a few thousand samples. RT-qPCR becomes an issue when dealing with a global pandemic with potentially millions of people to test. This leads to delays in testing as medical facilities become overwhelmed with requests.

IgG/IgM serological tests offer some advantages over RT-qPCR. Firstly, serological tests detect human antibodies (proteins belonging to the immunoglobulin class) which are known to be much more stable than viral RNA.

As a result, IgM/IgG serological specimens are less sensitive to spoilage during collection, transport, storage and testing than RT-qPCR specimens.



Secondly, because antibodies are typically uniformly distributed in the blood, serological specimens have much less variations than nasopharyngeal viral RNA specimens and can be easily collected with minor phlebotomy discomfort to the patient. Thirdly, unlike RT-qPCR, serological tests can detect past infection because virus-specific antibodies (unlike viral RNA) can persist in the blood for several weeks/ months after onset of symptoms.

While IgM/IgG serological tests alone may not be sufficient to diagnose COVID-19, they can be a valuable diagnostic tool when combined with RT-qPCR (see section below). In addition, because of their scalability, serological assays can be used in large-scale, whole-population, testing to assess the overall immune response to the virus and identify asymptomatic carriers of the virus. Indeed, 20-80% of COVID-19 cases are estimated to be asymptomatic[1].

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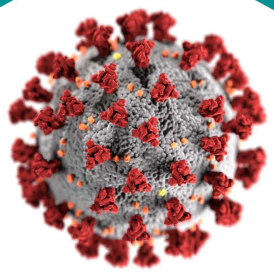

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HOW SHOULD WE INTERPRET IGM/IGG SEROLOGICAL TEST RESULTS?

Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. RT-qPCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

Table 1: Clinical Significance of an IgM/IgG Serological Test Result

The present IgM/IgG serological assay is designed to complement RT-qPCR in the diagnosis of SARS-CoV-2 infections. Table 1 shows the clinical interpretation of all possible scenarios that can be encountered when testing a patient with both RT-qPCR and an IgM/IgG serological test.

This table is based on the current knowledge about the rise and fall of SARS-CoV-2 RNA and antigens, IgM antibody and IgG antibody (Figure 1) and the correlation of these level variations with the initial time of infection, onset of symptoms and recovery phase[2-4].

As shown in Figure 1, serological tests are recommended to be used on patients at least 3 days after onset of symptoms or 7-10 days after infection with the virus[2-4].

The key takeaway is that the results of RT-qPCR and IgM/IgG serological tests do not necessarily need to agree. A disagreement between the two tests, if any, can often be traced to the after infection time points at which the tests were performed. Overall, while RT-qPCR testing may be appropriate for the detection of the SARS-CoV-2 virus during the acute phase, IgM/IgG is an appropriate test during the chronic phase. Since the exact time of infection is often unknown, combining RT-qPCR and IgM/IgG testing can improve the accuracy of the COVID-19 diagnosis.

References:

1. Li R, Pei S, Chen B, Song Y, Zhang T, Yang W, Shaman J2. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV2). Science. 2020 Mar 16. pii: eabb3221.

2. Lauer, S. et al., 2020. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Annals of Internal Medicine.

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4. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC et al. (2020). Temporal profiles of viral load in posterior oro-pharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020 Mar 23. pii: S1473-3099(20)30196-1.

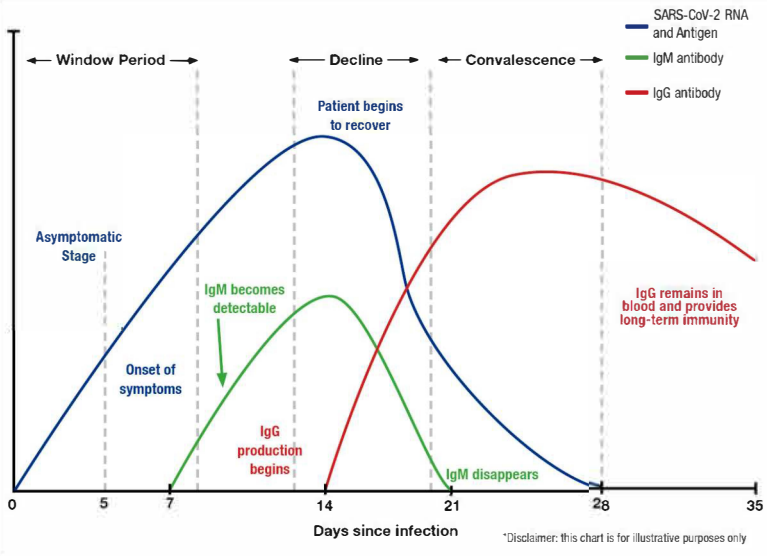

Figure 1: Variation of the Levels of SARS-CoV-2 RNA and Antigen, IgM and IgG after infection.