

## SARS CoV-2 IgM and IgG Frequently Asked Questions (FAQ)

### 1. What is SARS-CoV-2 and What is COVID-19?

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is the official name of the novel coronavirus that is currently causing a worldwide pandemic. COVID-19 is the official name of the respiratory disease caused by SARS-CoV-2. SARS-CoV-2 is highly contagious and is transmitted through respiratory droplets and contact with contaminated surfaces. More information about COVID-19 can be found at the Center for Disease Control and Prevention CDC website: <https://www.cdc.gov/coronavirus/2019-nCoV/index.html> and <https://www.coronavirus.gov/>

### 2. What is the Incubation Period for COVID-19?

Although several studies are still in progress, according to the March 10<sup>th</sup>, 2020 study published in the Annals of Internal Medicine, the incubation period for COVID-19 as measured from publicly confirmed cases is as follows<sup>1</sup>:

- Median Incubation period: 5.1 days (95% confidence interval, 4.5 to 5.8 days)
- 97.5 % of those who develop symptoms will do so within 11.5 days (CI, 8.2 to 15.6 days)
- These estimates imply that under conservative assumptions, 101 cases out of 10,000 cases (99th percentile, 482) will develop symptoms after 14 days of active monitoring or quarantine.

<sup>1</sup>Lauer SA, Grantz KH, Bi Q, Jones FK, Zheng Q, Meredith HR, Azman AS, Reich NG, Lessler J. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Ann Intern Med. 2020 Mar 10.

### 3. How Do SARS-CoV-2 IgM and IgG CLIA test Work?

- The SARS-CoV-2 IgM CLIA test is a capture chemiluminescence immunoassay. Using a fully automated chemiluminescence analyzer, the blood sample of a patient goes through a series of treatments with various reagents to generate a light signal that is proportional to the concentration of SARS-CoV-2 IgM antibodies.
- The SARS-CoV-2 IgG test is an indirect chemiluminescence immunoassay. Using a fully automated chemiluminescence analyzer, the blood sample of a patient goes through a series of treatments with various reagents to generate a light signal that is proportional to the concentration of SARS-CoV-2 IgG antibodies.

### 4. What is an IgM and What is an IgG?

Upon infection with the SARS-CoV-2 virus, the patient's immune system tries to fight the virus by producing blood-circulating molecules known as antibodies. IgM is a class of antibodies that appears early after an infection (as early as 3-5 days). IgM is the body's first line of defense against a foreign antigen. IgG is another class of antibodies that appears later and gradually replaces the IgM antibodies. Usually, IgG antibodies appear in the blood circulation within 3-4 weeks after initial infection. The presence of SARS-CoV-2-specific IgM and/or IgG antibodies in the blood of a patient is a strong indication that the patient has been infected with the SARS-CoV-2 virus.



## 5. What are the SARS-CoV-2 IgM and IgG tests?

- The SARS-CoV-2 IgM test specifically detects the presence/ absence of COVID-19-specific IgM antibodies in the blood of a patient.
- The SARS-CoV-2 IgG test specifically detects the presence/ absence of COVID-19-specific IgG antibodies in the blood of a patient.
- A positive test for either SARS-CoV-2 IgM or SARS-CoV-2 IgG provides a strong evidence of the infection of a patient with the SARS-CoV-2 virus. A positive test for SARS CoV-2 IgM indicates that the infection was recent. A positive test for SARS CoV-2 IgG indicates that the patient had an infection for at least 3 weeks or more. Since most patients do not know the exact time when they contracted the virus, the combining both IgM and IgG tests provides a much higher test sensitivity and test specificity.

## 6. How Are the SARS CoV-2 IgM and IgG Tests Useful?

- The presence of SARS-CoV-2 IgM or IgG antibodies in the blood of patient provides a second and independent evidence of the infection of a patient who may have been tested positive with the standard nucleic acid test (RT-qPCR test). Both IgM and IgG assays double confirm the accuracy of the RT-qPCR test results as it is known that RT-qPCR test may give false negative results when the sampling procedure is inadequate or inappropriate. The serological tests for IgM and IgG can also provide earlier detection of potential positive patients who may not have immediate access to the RT-qPCR test.
- The SARS-CoV-2 IgM/IgG CLIA tests can be used to complement the RT-qPCR tests for an accurate diagnosis of current infection in patients showing COVID-19 symptoms.
- The tests can also help investigate some of the false negative results observed with RT-qPCR and that can be due to insufficient or poor nasopharyngeal sampling.
- The SARS-CoV-2 IgM/IgG CLIA serological tests for IgM and IgG are similar to those routinely used in the diagnosis of influenza.
- Because of their higher throughput and lesser complexity, they can ease the burden on the current nucleic acids-based assays (NAT).
- Unlike NAT assays, the SARS-CoV-2 IgM/IgG CLIA serological tests have less preclinical requirements and do not involve complex extraction procedures.

## 7. How Are the SARS CoV-2 IgM and IgG different from RT-qPCR?

The current nucleic acid test for SARS-CoV-2 is based on the detection of the viral ribonucleic acid (RNA) using a modified version of the polymerase chain reaction technique (RT-qPCR). Although the test is sensitive, it suffers from several limitations that include:

- Low throughput.
- High complexity: Several manual steps are required by highly trained personnel
- Variability in accuracy: The test may not detect patients who have been previously infected but have since recovered.
- Variations in nasal swab-based sampling which may lead to false negative results.





### **The new SARS-CoV-2 IgM CLIA and SARS-CoV-2 IgG CLIA tests have/are:**

- Much higher throughput: First results appear after 34 min, which makes large scale testing possible.
- Less complex: The FDA recognizes that serology tests are less complex than molecular tests. Especially, since current IgM/IgG tests are fully automated.
- Capable of detecting patients who were infected with the virus but have since recovered. This is due to the fact that SARS-CoV-2 antibodies can remain in the blood of a patient for a long period of time after the onset of an infection.

### **8. What is the current Throughput of the SARS-CoV-2 IgM and IgG tests?**

When running both the IgM and IgG tests in parallel, Labtech Diagnostics current throughput is estimated at 1200 tests a day. However, Labtech Diagnostics can scale up its throughput based on test demand.

### **9. What Type of Samples Can I Use with the SARS-CoV-2 IgM and IgG tests?**

Serum and EDTA plasma samples can be used with the SARS-CoV-2 IgM and IgG assays.

### **10. How do I Ship Specimen to Be Tested with the SARS-CoV-2 IgM and IgG to Labtech Diagnostics?**

It is recommended to ship samples at 2-8°C using an overnight freight service. Alternatively, samples can be shipped frozen.

### **11. Why are the SARS-CoV-2 IgM and IgG CLIA Tests Important during the Current Pandemic?**

Controlling the spread of the SARS-CoV-2 virus relies heavily on the fast and accurate identification of the infected persons and their isolation from the general population. With the exponentially increasing number of people showing COVID-19 symptoms, large-scale testing of symptomatic populations is now inevitable. With its high-throughput and low complexity, SARS-CoV-2 CLIA IgM/IgG tests offered by *Labtech Diagnostics* are suitable for large scale roll out of SARS-CoV-2 testing and can adequately complement the RT-qPCR test results in patients with active infections. Additionally, the new tests can help identify patients who were infected early on and who have since recovered. In conjunction with other tests, the SARS-CoV-2 IgM/IgG tests can help decision makers at the local, state and federal levels take the appropriate confinement measure to slow the progression of the SARS-CoV-2 outbreak.



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