

FAQ for Antibody Test Result

1. What is the Covid-19 rapid antibody test and why we do it?

The COVID-19 IgG and IgM Serology Rapid Antibody Test is a lateral flow immunoassay used to detect IgG and IgM antibodies against SARS-CoV-2 in whole blood, serum, or plasma.

Due to its ease of use, Serology Rapid Antibody Tests are used for large-scale, whole-population, testing to assess the number of people in a community who has had exposure to SARS-CoV-2. Individuals with known exposure to SARS-CoV-2, having symptoms and confirmed to have COVID-19 with a nucleic acid amplification test and are positive for presence of antibody are called 'documented infections'. People without any of those known exposures or confirmations who are positive for presence of antibody are called 'undocumented infections', or asymptomatic cases. Serology Rapid Antibody Tests (or any other antibody test) could detect the antibody in the person regardless of their status as documented or undocumented infection, symptomatic or asymptomatic.

2. How accurate is the test result?

The accuracy of these tests is described by their "sensitivity," or their ability to identify those with antibodies to SARS-CoV-2 (true positive rate), and their "specificity," or their ability to identify those without antibodies to SARS-CoV-2 (true negative rate). A test's sensitivity can be estimated by determining whether or not it is able to detect antibodies in blood samples from patients who have been confirmed to have COVID-19 with a nucleic acid amplification test, The rapid test being used by BowTie Medical meets the threshold set by FDA on sensitivity and specificity.

3. What is IgG and IgM?

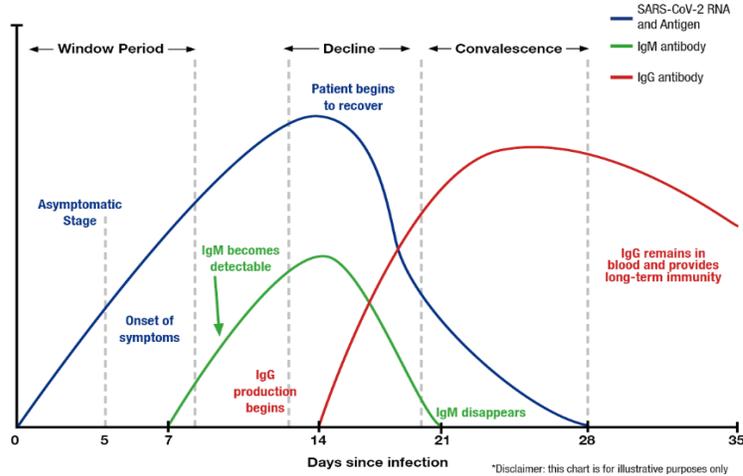
Upon infection with the SARS-CoV-2 virus, the patient's immune system tries to fight the virus by producing blood-circulating molecules known as antibodies, called immunoglobulin (Ig).

IgM is usually the first antibody produced by the immune system when a virus attacks and appears early after an infection (as early as 3-5 days). A positive IgM test indicates that you may have been infected and that your immune system has started responding to the virus. When IgM is detected you may still be infected, or you may have recently recovered from a COVID-19 infection.

IgG appears later and gradually replaces the IgM antibodies. Usually, IgG antibodies appear in the blood circulation within 3-4 weeks after initial infection. A positive IgG indicates that you may have had COVID-19 in the recent past and have developed antibodies that may protect you from future infection. At this point, it is unknown how much protection antibodies might

provide against reinfection. Figure 1 below shows the natural history of build up of antibody against SARS-CoV-2.

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.



4. How to interpret Covid-19 IgG/IgM serological test results?

A total of three detection lines are possible for Serology Rapid Antibody Tests, with the control (C) line appearing when sample has been flowed through the test cassette. (shall we put a picture here?)

Test Result		Interpretation	Clinical Significance
IgG	IgM		
-	-	Negative	Patients may be not infected or in the window period of infection.
-	+	IgM Positive	Patients may be in the early stage of infection.
+	-	IgG Positive	Patient may already recovered or in the late stage.
+	+	IgM/IgG Positive	Patients may be in the active or recovery stage of infection.

5. Why would I test positive when I have not had any symptoms such as fever, dry cough, and shortness of breath?

Individuals with known exposure to SARS-CoV-2, having symptoms and confirmed to have COVID-19 with a nucleic acid amplification test and are positive for presence of antibody are called 'documented infections'. People without any of those known exposures or confirmations who are positive for presence of antibody are called 'undocumented infections', or asymptomatic cases.

If you've been exposed to someone with SARS-CoV-2, you should self-quarantine for the entire 14-day incubation period. Even if you feel fine, you're still at risk of spreading the coronavirus to others.

6. What to do next after the IgG/IgM serological test?

If you test positive for presence of COVID-19 antibodies, you have antibody, which means you are recovering and IgG may protect you against SARS-CoV-2. If you are interested in learning how long your immunity will last, we would recommend repeat of the test in 4-6 weeks time.

If you test negative for presence of COVID-19 antibodies, one of three scenarios may exist: i) you have not had any exposure to SARS-CoV-2, ii) your exposure is too recent (0-3 weeks) and you have not yet developed any antibody, or iii) you don't form antibody against SARS-CoV-2 (this has been seen with other viral infections such as Hepatitis B, where 10-20% of individuals do not form antibody to HepB Virus). Since we still don't know a lot about SARS-CoV-2, we recommend a consultation with a physician if our explanation is not sufficient for you.

Regardless of your response to serology tests, we recommend that you still follow the CDC guidance for COVID-19 Pandemic: Wash your hands often, avoid close contact, cover your mouth and nose with a cloth face cover when around others, cover coughs and sneezes, clean disinfect, and follow social distancing practices.

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

7. Introduction of BowTie Medical

BowTie Medical is a healthcare organization that aims to integrate three prongs of "care", "advice" and "savings" in order to improve the health of an individual and reduce cost by reducing waste, eliminating unnecessary care and restoring control of health care to the individual customer as a member.

Currently, we are providing *60 Day Coronavirus Care Program*. This limited 60-day plan is designed to help you go through the worst of the pandemic. Services include:

- A personalized COVID-19 risk report.
- 24/7 Virtual access to Doctors and Nurses if you have symptoms of illness.
- Access to health advisers for your questions and concerns.
- Secure personal portal with messaging, laboratory and imaging testing (if needed) and prescriptions if necessary.