



## COVID-19 IgG/IgM RAPID TEST INTRODUCTION

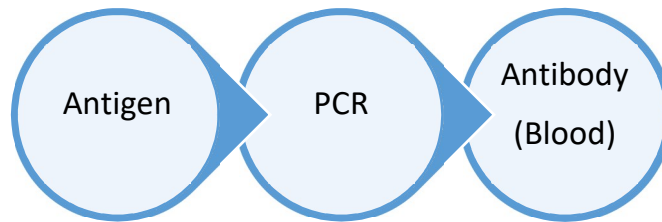
The 2019 Novel Coronavirus (COVID-19) is highly contagious and has spread rapidly throughout the world. To curb the spread of the virus and get the population back to some normalcy, efficient and accurate testing must be at the forefront of the strategy to combat this virus, along with contact tracing and quarantines for the infected.



Serology antibody testing is currently the most critical step in solving this problem. The ability to perform serology antibody tests millions at a time, accurately and reliably is also important.

# CURRENT TESTING METHODS

The three methods of testing for COVID-19 are the antigen test, the PCR test, and the antibody test.



1. The antigen test can be performed rapidly which checks the presence of viral particles in the nose or mouth. This test has significant flaws due to the fact that there are many false negatives and false positive test results (1). It can be done rapidly which is an advantage. But due to this inaccuracy, this is not a reliable way to determine whether or not a person has the active infection of COVID-19 and whether or not a person can safely go back to work without flaws.
2. The second approach is a PCR test, which checks the genetic material of the virus. The advantage/disadvantage of this test is that it is a very sensitive test, but it is too sensitive. The high sensitivity means that it can detect very small amounts of this virus, much smaller amounts than the antigen test as mentioned above. As a consequence, a false negative result is not its limitation. The limiting aspect of the PCR test is that it has too many false positive results. This means that it detects when there may be only trace amounts of the virus that is too minute to cause any infection. A positive PCR test may not accurately indicate that an individual has the infection, and not accurately able to determine that an individual is not able to transmit the COVID-19 viral infection to others. This potential false sense of determination of being infectious and contagious can result in quarantining, missing work, and missing school unnecessarily.

Using the above two methods of viral detection to determine if an individual is safe to participate in work or school, travel or other aspects of the public domain not only have the flaws as described above, but the results of these tests will require additional efforts: These two tests need to be integrated and interpreted along with the CDC guidelines and/or a physicians' recommendations based on onset of symptoms, known or unknown exposures to others with the COVID-19 infection. Additionally, most labs offer the antigen and PCR test with a turnaround in the number of days to weeks. While these tests have their role during this pandemic, getting people back to work will necessarily require something better: antibody testing.



## Covid-19 IgG/IgM Rapid Test

- ▶ EASY TO DO
- ▶ RESULTS IN 10 MINUTES
- ▶ HIGH SPECIFICITY AND ACCURACY

3. Antibody testing is reliable, quick and easy to perform, relatively inexpensive, and a positive result is not mired with the significant false information that requires combining the results with additional clinical information. A positive antibody test is one in the same as knowing if a person is vaccinated. Given the fact that a vaccination is not yet available, this is not an option. Detecting those individuals who have immunity against the virus with antibody testing after is equally as advantageous as knowing who is vaccinated.

Antibody testing can be done rapidly by taking a blood sample with a finger stick (similar to the way a diabetic patient checks his or her own glucose-but even easier because there is no electronic device necessary). The results of this antibody test will be known within 10 minutes. This method is extremely accurate, appropriately sensitive, and can also indicate recent or current infection or exposure (to ascertain immunity).

Determining whether or not a person has immunity to this virus is similar to what would be found if a person were to be vaccinated. Up until now, without a vaccine, the only way in which we know if the person has immunity to this virus is after they have had a COVID-19 viral infection Along with a positive antibody test.

## HOW DOES IT WORK?

1. Collect blood sample after the finger stick with the lancet
2. Add blood to the sample well labeled S
3. Place 3 drops of buffer in the sample well labeled D
4. Wait 10 minutes
5. Read results

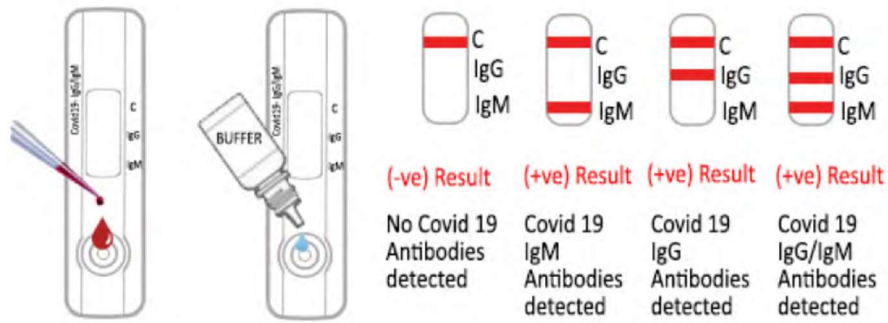


The COVID-19 IgG/IgM Rapid Test is a 10-minute chromatographic immunoassay test for the qualitative detection of IgG and IgM antibodies of COVID-19 in human blood, serum, or plasma.

Detection of either immunoglobulin IgM or IgG means that the subject has been infected by COVID-19 and should seek professional advice related to diagnosis and treatment.

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The antibody test checks for 2 antibodies: IgM and IgG. The IgM antibody is the antibody that is detected in the bloodstream from a recent or current infection. The IgM antibody disappears after approximately six weeks from symptoms. The IgG antibody is detected in the bloodstream when the infection is longer than two weeks post symptom onset, which is after an average three weeks from exposure to the virus. This IgG antibody can be long-lasting or in some patients can wane over a few weeks or a few months in others. The detection of an IgG response indicates the patient is no longer able to contract the COVID-19 infection and can no longer transmit the infection to others, in a similar manner that a vaccine would work.

The antibody test is therefore a superior solution to the Antigen and PCR test to ensuring safety in public exposure to an individual concerned with being exposed to the COVID-19 virus.

	ANTIGEN	PCR	ANTIBODY
<b>METHOD</b>	Nasal Swab	Nasal Swab	Finger Stick (Blood)
<b>TIMEFRAME</b>	Rapid (~10 Minutes)	Slow (~2-5 Days)	Rapid (~10 Minutes)
<b>ACCURACY</b>	Low	Mid-High (Overly Sensitive-False Positives)	High
<b>COST</b>	Low	High	Low
<b>HOW IT WORKS</b>	Requires nasal swab to check presence of viral particles. Only capable of indicating current infection. Many false test results due to human error.	Requires nasal swab to check for traces of virus' genetic material. Capable of indicating current or recent infection. Virus traces detected may too negligible to cause infection and the patient would be asymptomatic and not contagious = False Positive	Requires finger prick blood test and checks for IgM and IgG antibodies. Capable of indicating current or recent infection via IgM antibodies and current viral immunity status via IgG antibody detection.

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