



COVID-19

As you know, antibody testing for COVID-19 has recently become widely available with multiple laboratories, like LabCorp and Quest, engaged in direct-to-consumer advertising. At the same time, numerous companies are advertising finger-stick antibody tests. Often, these non-serum-based tests undergo fast-tracked EUA approval and their sensitivity and specificity are difficult to decipher.

At this time, the WHO, CDC, and the State of Maryland do not endorse using these results for individual clinical decision making due to insufficient data to support interpretation. Nonetheless, we are aware that many patients and organizations are asking for antibody testing. As the largest healthcare provider in the region, it is our responsibility to counsel our patients appropriately with the most up-to-date information regarding antibody testing and to enable them to undergo testing using the most evidence-based platform if they advocate for such a test. More importantly, our group of highly-skilled providers can offer pre- and post-test counseling to put the test results into perspective as many patients may not be able to access this elsewhere.

With this in mind, MedStar Health believes that patients and their providers should undergo a shared decision-making process regarding antibody testing.

What you need to know:

Testing Platforms: MedStar Health uses the ELISA serum (blood draw) test for IgG antibodies with the DiaSorin analyzer. The DiaSorin test has a sensitivity of 97.4% and specificity of 98.5% making it one of the best tests currently available. Other national reference laboratories such as LabCorp and Quest use a similar platform to perform antibody testing. Therefore, those results can be interpreted in a similar way.

What the test cannot tell us: Regardless of test result, we do not know whether the presence of antibodies confers immunity. Therefore, patients who test positive for the presence of antibodies should still practice physical distancing, masking, and other precautions. More importantly, given the low prevalence of disease, the test currently carries a significant likelihood of false positive results (see below).

Testing Limitations: As with all tests, the positive and negative predictive values (PPV and NPV, respectively)—the proportion of tests that are **true** positive and **true** negative results—depend on the prevalence of disease. It is important to note that although we do not know the exact prevalence of COVID-19 in our population, we believe it to still be low at this time. Undergoing a second antibody test may help improve those pre-test probabilities. Also, as the prevalence of COVID-19 in our community continues to rise, the PPV will improve and NPV will become worse.



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JOB AID #1

Example: given an estimated 5% prevalence in our community, we would expect the PPV of the test to be 77%. That mean that roughly 1/4 of all people who test positive for COVID-19 antibodies would have a false positive test result. On the other hand, the negative predictive value is over 99%. That means that we expect all people who test negative for the presence of antibodies to not have any antibodies present. As the prevalence of COVID-19 in our community continues to rise, the PPV will improve and NPV will become worse. For sample calculations, please see below.

MedCalc: Bayesian Analysis Model

Enter **PREVALENCE**, **SENSITIVITY**, and **SPECIFICITY**:

PREV: SENS: SPEC:

Or enter **TP**, **FN**, **TN**, and **FP**:

N = 1000	Disease	No Disease
Positive Test	TP: <input type="text" value="49"/>	FP: <input type="text" value="14"/>
Negative Test	FN: <input type="text" value="1"/>	TN: <input type="text" value="936"/>

Positive Predictive Value =

Negative Predictive Value =

Positive Likelihood Ratio = Pre-test Probability = (prevalence)

Negative Likelihood Ratio = Post-test Probability =

Possible scenarios and explanations:

If you had a viral syndrome and were diagnosed with COVID-19 using a swab test:

- And your serology test shows you are **IgG POSITIVE**, this likely confirms that you have been exposed to and produced antibodies to the virus, but:
 - The test does not determine whether you are still infected
 - The test does not guarantee that you are immune
- And your serology test shows you are **IgG NEGATIVE**, this does not mean that your initial diagnosis of COVID-19 was incorrect:
 - You may have produced a level of IgG that is too low to be measured by this test
 - You may not yet have produced an IgG antibody response to the virus



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If you previously had a viral syndrome but not formally diagnosed with COVID-19 using a swab test, or your swab test result was “Not Detected” or “Negative”:

- And your serology test shows you are **IgG POSITIVE**
 - This MAY indicate you were exposed to and produced antibodies to the virus; however, the PPV for a disease with a low prevalence is **low** and false positives are common.
 - Your previous viral syndrome MAY or MAY NOT have been COVID-19
 - The test does not measure the amount of antibody present
 - The test does not guarantee that you are immune
- And your serology test shows you are **IgG NEGATIVE**
 - You may not have been exposed to COVID-19
 - You may have been exposed to COVID-19 but produced too few IgG antibodies to be measured by this test

If you have had no viral syndrome or illness to date:

- And your serology test shows you are **IgG POSITIVE**
 - You may have a false positive
 - **The test does not guarantee that you are immune**
- And your serology test shows you are **IgG NEGATIVE**
 - You may not have been exposed to COVID-19
 - You may have been exposed to COVID-19 but produced too few IgG antibodies to be measured by this test