COVID-19 Antibody Testing Frequently Asked Patient Questions

Antibody Testing (Serology Testing)

What is an antibody?

- An antibody is protein that is a normal part of the immune response to many types of infections.
- Our bodies develop antibodies in the days and weeks after being infected.
- Antibodies are specific for different infections as part of the immune response, the antibody attaches to specific parts of the germ. For example, there are antibodies for influenza and different antibodies for hepatitis C.

What is an antibody test?

- An antibody test looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies to specific infections can be found in the blood of people who are tested after infection and show that people have had an immune response to the infection.
- An antibody test is a type of blood test to see if you have:
 - o Any antibodies for an infection (yes/no result also known as a "qualitative" test), or
 - How much antibody (a "quantitative" test)

Does Salem Health offer an antibody test for COVID-19?

- Yes, Salem Health Laboratories is pleased to announce that we are now offering COVID-19 antibody testing.
- The test is a "qualitative" test; it only can tell you if it detects antibodies to SARS-CoV-2 or not.

How accurate is the antibody test?

- It is very sensitive validation by our laboratory showed that by fourteen days after a positive acute COVID-19 diagnostic test (PCR) 100% of patients have a positive antibody test.
- It is very specific it will be negative in >99.9% of people who did not have an infection.
- One challenge with this test is that due to the overall low number of people with COVID-19 in the community, it is possible to have a "false positive" result. This means the test will be positive when the person never was infected. This is true for all antibody tests, including a very good one like the one used at Salem Health Laboratory.
- In some cases, immunocompromised patients may have a negative test result despite prior COVID-19 infection due to lack of or delay in development of detectable antibodies.



Has this test been approved by the Food and Drug Administration (FDA)?

- No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA).
- The test has been reviewed by the Food and Drug Administration, and granted an Emergency Use Authorization. The Emergency Use Authorization was granted on April 26, 2020.
- Salem Health Laboratories is performing the SARS-CoV-2 IgG assay under the Food and Drug Administration's Emergency Use Authorization. Testing is being performed on an Abbott Architect i1000.
 - o FAQ Sheet for Patients: https://www.fda.gov/media/137382/download
 - o FAQ Sheet for Healthcare Providers: https://www.fda.gov/media/137381/download

I have symptoms that I think might be COVID-19. Should I get this test?

- No. The antibody test is not used to diagnose acute infections. If you have any symptoms concerning for COVID-19 (fever, feeling short of breath, cough, muscle pain, sore throat, loss of taste or smell, new diarrhea) you should talk to your healthcare provider about getting a different test (usually a PCR test) that looks for the virus itself.
- Because antibodies do not usually develop until days to weeks after infection, we cannot depend on them for diagnosis.

I want to get tested to see if I had COVID-19. Can I just go to a hospital or clinic and get tested?

No. You should talk to your healthcare provider to learn about the test and to determine whether
you should get this test. The test requires an order from your provider and then a blood draw by a
qualified healthcare professional.

If not used for diagnosis of COVID-19, why would I get an antibody test?

- The antibody test can confirm that you had a past COVID-19 infection if you had COVID-19 symptoms (fever, tiredness, dry cough, aches and pains, sore throat, diarrhea) more than two weeks ago but were not able to access diagnostic PCR testing to confirm the infection.
- If your test is negative (and you have no symptoms), it means you likely have not had a COVID-19 infection.
- If your test is positive, it is likely that you were infected at some point in the last several months, but the result may also be a "false positive" (discussed above). This means that result is positive even though you were not exposed to the virus.
- This type of test will help public health departments and researchers learn more about how many people in a population have been exposed or infected.
- If you are interested in getting tested, you should discuss with your healthcare provider.



Does a positive antibody test result mean I am immune?

- We do not yet know if a positive test result means that a person is immune, and if it does, for how long immunity might last. We hope to learn more about these questions in the coming months.
- If your test is positive, you should continue to follow public health recommendations on social/physical distancing, hand hygiene, environmental cleaning, staying home when ill and mask use.

What does a positive result mean?

A positive result means that you were most likely exposed to SARS-CoV-2 and have developed
antibody directed against the virus. A positive result, however, does not correspond to a level of
immunity. Studies are not yet available to demonstrate if antibody presence is capable of
preventing repeat infection. As mentioned above, you should continue to follow public health
recommendations on social/physical distancing, hand hygiene, environmental cleaning, staying
home when ill and mask use.

What does a negative result mean?

- A negative result means one of the following:
 - You were most likely not infected with the SARS-Cov-2 virus.
 - You had a mild case or mild infection that did not result in sufficient production of SARS-CoV-2 IgG antibodies to be detectable by this test.
 - You had a specimen collected too soon after onset of symptoms to have developed detectable antibodies. In most cases, antibodies are typically detectable at 14 days after onset of symptoms. However, this is dependent on each individual, and may be different in patients with poor immune response or that are immunocompromised.

Can my family and friends get the test?

• During the dates of May 13-20, we will prioritize health care workers. Afterward, the general public can request the test from their PCP. The general public will be asked to use our labs other than the Salem Hospital campus, which include the Regional Lab on State St. and our labs in Monmouth, Dallas and Woodburn.

My healthcare provider is located outside the Salem area, can they still order my test?

 Yes. Salem Health Laboratories accepts orders from all providers, not just those that practice in the Salem area.

Is there financial assistance for this test?

• Salem Health is committed to making sure our patients get the hospital care they need regardless of their ability to pay for that care. Providing health care to those who cannot afford to pay is part of our mission, so we provide free and discounted care to eligible patients. For assistance in better understanding costs and estimates given your personal situation, please call our estimates team at 503-814-2678 or email at estimates@salemhealth.org.



Will my health plan pay for this test?

• We recommend patients reach out to their health insurance company for coverage costs.

What instrument does Salem Health Laboratories use to perform this test?

- Salem Health Laboratories is performing the SARS-CoV-2 IgG assay under the Food and Drug Administration's Emergency Use Authorization. Testing is being performed on an Abbott Architect i1000.
- Test Menu Information: https://www.testmenu.com/salemhealthlab/Tests/1038513

