

Serological tests detect antibodies in the blood generated as part of the immune response to a specific infection, such as infection with SARS-CoV-2, the virus that causes COVID-19. Antibody tests are different from tests such as polymerase chain reaction (PCR) and antigen tests which detect the SARS-CoV-2 virus. Many new serological tests for COVID-19 have been developed and have an emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA). Only antibody tests that have an FDA EUA should be used. The Idaho Division of Public Health discourages the use of unauthorized serology-based assays for diagnosis of COVID-19 or determining if someone is currently infected or had a prior infection.

Serological tests are not recommended for COVID-19 diagnosis in most situations because it takes usually 10 or more days after SARS-CoV-2 infection before serology tests become positive. However, serologic tests may be helpful in diagnosing a COVID-19 infection when used with PCR among patients who do not come to medical care until later in their illness when they may no longer be shedding virus and, thus, PCR testing may no longer be positive.

People in the early stages of COVID-19 might test antibody negative despite being highly infectious. Additionally, some tests might give a false positive result because of past or present infection with other types of coronaviruses. False positive results are also more likely when the percentage of the population with the disease is low. The Idaho Division of Public Health discourages persons who have a positive serology test from relaxing the precautions such as social distancing that are recommended for all Idahoans to prevent spread of coronavirus, and strongly discourages employers from relaxing the employee protections for an employee solely based upon a positive serology test.

The immune response to SARS-CoV-2 (the virus that causes COVID-19) infection is not well understood. It is not known whether the antibodies detected by serological assays provide immunity to reinfection or how long antibody from prior infection can protect against reinfection.

CDC has updated information on the use of antibody testing at [www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests.html](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests.html). And the State of Idaho Testing Task Force recommendations can be found at: <https://coronavirus.idaho.gov/idaho-resources/>.

## FAQs

### **Which serological tests have been authorized by the FDA?**

The FDA updates a list of diagnostic tests that have received an EUA at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

### **What is the difference between IgM and IgG? What does it mean if I am positive for one but not for the other?**

In general, IgM antibodies are produced earlier in response to an infection compared to IgG, and IgG antibody is generally longer lasting. However, the CDC currently does not identify any advantage to tests that detect IgG, IgM and IgG, or total antibody.

### **How accurate are the available serological tests?**

The accuracy of currently available antibody tests is variable. Whether a test result accurately tells if you have or do not have the disease partly depends on the percentage of the population that has the disease – the lower that percentage, the less accurate that result is. Information on the accuracy of different serology tests with an FDA EUA can be found at: [www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

### **If a person's blood sample tests negative using a serological test, does that mean that the person does not have COVID-19?**

Not necessarily. The person might be in the early stages of COVID-19 infection and has not developed enough antibodies to be detected by a serological test. Results from antibody testing alone are not enough to determine whether someone is infected with SARS-CoV-2. Also, not everyone who has had COVID-19 will have a positive antibody test.

### **If a person's blood sample tests positive using a serological test, does this mean that this person is immune to COVID-19?**

We do not know yet whether people who test positive by a serological test are immune to COVID-19 or, if they are immune, how long that immune protection will last. In addition, some people will have a test that shows an immune response, but the result is not accurate.

### **I was tested and told I have antibodies to COVID-19. How long will they last?**

It is not known how long antibodies will last following COVID-19 infection.

### **How do we know if someone who had COVID-19 is still infectious?**

Antibody tests do not tell us whether a person is infectious. The CDC has issued guidance for determining when a person with confirmed or suspected COVID-19 can be released from isolation, meaning that they are no longer considered infectious.

### **What does it mean if I test positive for COVID-19 using a serological test?**

A positive serology test means that you might have antibodies to the virus that causes COVID-19, indicating that you were infected by the virus that COVID-19 in the past or might be currently infected, depending on the type of antibodies detected. However, there may be a significant chance that a test can give the wrong result, called a false positive, because of cross-reacting antibodies from previous infections such as from a prior infection with a different human coronavirus.

## **What does a rapid COVID-19 test mean?**

A rapid test means that the test results are available in a relatively short time frame, typically less than one hour. For COVID-19, there are two types of rapid tests. Rapid serology tests detect antibodies, whereas rapid diagnostic tests (sometimes called point-of-care diagnostic tests) detect the virus that causes COVID-19.

## **I'm not sick, but my employer says I need to be tested for COVID-19 before I come back to work. Is that legal? Can I even get a test if I'm not sick?**

Employers can send symptomatic workers home and can conduct screening procedures such as checking employee's temperatures before they enter the building. Employers can require a doctor's note before allowing someone who has been sick to return to work, but they cannot require employees to have a medical procedure such as a blood test. Most healthcare professionals will only offer COVID-19 testing to symptomatic patients in most circumstances. The Idaho Division of Public Health does not recommend that employers use coronavirus serology testing to make determinations as to whether employees present a risk of infection, whether employees are medically cleared to return to work outside of healthcare settings, or whether employees are immune to SARS-CoV-2 and therefore do not need to utilize all the protective measures that other susceptible employees are required to use.

## **I tested positive for antibodies to COVID-19. Is it safe to take care of my elderly parents without wearing a mask or face covering?**

A test for antibodies does not tell you whether you currently have the COVID-19 virus. Cloth face coverings are recommended to reduce the risk of potentially spreading COVID-19 to others.

## **Will DHW or the local public health districts be issuing immunity passports?**

No It is not known whether people who have recovered from COVID-19 are immune from reinfection or how long antibody from prior infections lasts.

## **If I test positive on an antibody test, do I still need to get vaccinated when a vaccine is available?**

It is not known whether antibodies detected using serology tests protect against future COVID-19 infections or for how long that protection might last. Guidance on who should get vaccinated will be provided when there is a licensed COVID-19 vaccine available.

## **It sounds like a lot is unknown about what a SARS-CoV-2 antibody test really means. What are they good for?**

Antibody tests might be most useful for estimating the percentage of people in a group that have already been infected and for estimating changes in the percentage of people with SARS-CoV-2 antibody in a community over time. The Idaho Division of Public Health does not recommend the use of antibody tests alone to advise individual patients about whether they have had COVID-19 or are infected with SARS-CoV-2. Antibody testing may also be helpful with done with PCR testing for persons who come to medical care later during an illness suspected of being COVID-19 when PCR testing may no longer be positive.