Serological (Antibody) Testing for COVID-19

Serological tests detect antibodies in the blood generated during the immune response to a specific infection, such as COVID-19. They are different from tests such as PCR that detect the virus that causes COVID-19. Many new serological tests for COVID-19 have been developed; however to date only four have been authorized by the Food and Drug Administration (FDA). Some companies are falsely claiming their serological tests have been approved by the FDA or that they can diagnose COVID-19 infections. **The Idaho Division of Public Health discourages the use of unauthorized serology-based assays for diagnosis of COVID-19 or determining someone's infectious or immune status.**

Rapid serological tests are not recommended for COVID-19 diagnosis. They detect antibodies generated over time as the body responds to an infection, typically in the second week after a person develops symptoms. People in the early stages of COVID-19 might test 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 form 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.

FAQs

Which serological tests have been authorized by the FDA?

As of April 15, 2020, the FDA has issued Emergency Use Authorizations (EUA) for four serological tests for COVID-19. All four of these are authorized for use in certified diagnostic laboratories.

- qSARS-CoV-2 IgG/IgM Rapid Test by Cellex, Inc.
- VITROS Immunodiagnostics Anti-SARS-CoV-2 Total Reagent Pack by Ortho Clinical Diagnostics
- DPP COVID-19 IgM/IgG System by Chembio Diagnostic
- COVID-19 ELISA IgG Antibody Test by Mount Sinai Laboratory

The full list of diagnostic tests that have received an EUA is posted at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

Why are unauthorized tests available?

In March, the FDA issued a policy to allow developers of certain serological tests to begin to market or use their tests once they have performed an evaluation to determine whether their tests are accurate and reliable. This includes allowing developers to market their tests without prior FDA

review if certain conditions are met. These tests may only be legally used by certified diagnostic labs. These tests are not approved or authorized by the FDA.

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

IgM antibodies are produced in the early stages of an infection, whereas IgG antibodies generally do not begin to appear until 7 to 10 days after infection. Testing positive for IgM only, or both IgM and IgG suggests you might have a current or recent infection with the SARS-CoV-2 virus. Testing positive for IgG only suggests that you might have had a previous or recent infection with the SARS-CoV-2 virus.

How accurate are the available serological tests?

The accuracy of currently available tests is highly variable. Tests that have been authorized by the FDA generally have been shown to perform well. 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. For questions regarding the how well a particular test works, ask your healthcare provider (if they are the one recommending the test) or consult the manufacturer.

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.

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.

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 symptom-based 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. These criteria are as follows: at least one week after illness onset, no fever, and symptoms have improved for 72 hours.

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 those caused by other human coronaviruses.

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. **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 utilize all the protective measures that other susceptible employees are required to use.**

I test 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 masks and face coverings are recommended to reduce the risk of potential spread to others.

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

No. Currently, there is no way to tell whether someone is immune to COVID-19. It is not known whether people who have recovered from COVID-19 are immune from reinfection.

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 as this will depend on several factors such as the type of vaccine.

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.

If I donate blood or plasma, will I get tested for antibodies against COVID-19?

The Red Cross is not currently routinely testing for antibodies to SARS-CoV-2.

Where can I donate my plasma so other people can benefit from my antibodies?

The Red Cross has partnered with the FDA to identify eligible people who have recovered from COVID-19 to donate plasma. See the Red Cross website for more information: https://www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html