

COVID-19 Serology Testing Public Guidance

Rapid Serology Tests

The market is flooded with commercially available so called “rapid serology tests” that resemble home pregnancy tests. The technology is a lateral flow immunoassay performed on a finger-stick blood sample. They are of uncertain reliability and not recommended for individual use since the results – whether positive or negative – are inconclusive. Since the FDA did not require Emergency Use Authorization, many of these disposable tests have not been fully validated and the performance characteristics are not well established.

It’s critically important to know that:

- A positive result does not indicate protection from future COVID-19 infections and does not definitively indicate prior exposure to COVID-19.
- A negative result does not exclude either current or prior COVID-19 infection.

Below are answers to frequently asked questions regarding Rapid Serology Tests:

I had a rapid blood test for COVID-19 and it’s positive. Does it mean I’m protected from COVID-19?

A positive result from a rapid disposable serology test **does not indicate** protection from future COVID-19 infections and does not definitively indicate prior exposure to COVID-19. In fact, very little is known at this time about what it means to have a positive result from a rapid serology test. The disposable test kits have not been vetted by the FDA and are of uncertain reliability. It will be important for you to follow-up with your doctor who may order confirmatory testing with a swab for molecular testing or a blood draw for a serology test performed at a lab.

I had a rapid blood test for COVID-19 and it’s positive. What should I do next?

It means that you *may* have been exposed to a coronavirus, including COVID-19 (novel coronavirus). However, very little is known at this time about what it means to have a positive result using a rapid disposable serology test. The disposable test kits have not been vetted by the FDA and are of uncertain reliability. It will be important for you to follow-up with your doctor who may order confirmatory testing with a swab for molecular testing or a blood draw for a serology test performed at a lab.

I had a blood draw for a COVID-19 serology test performed in a laboratory and it’s positive. Does it mean I’m protected from COVID-19?

A positive serology test means that you have developed an antibody response to a coronavirus, possibly COVID-19 (novel coronavirus) but it is not known at this time if the response is partially or fully protective against future infections. Please follow-up with your doctor who may perform further evaluation with a swab for molecular testing since a positive serology test cannot distinguish between a current active vs. prior resolved COVID-19 infection

I had a blood draw for a COVID-19 serology test performed in a laboratory and it’s negative. Does it mean I don’t have COVID-19?

A negative serology test means that you have not developed an immune response to COVID-19. However, it does not necessarily mean that you don't have a COVID-19 infection. It can take 1-2 weeks after onset of symptoms for an immune response to develop. If you are not feeling well, please follow-up with your doctor who may perform further evaluation with a swab for molecular testing.