

# Educate About Limitations of COVID-19 Antibody Testing

You'll get **questions about antibody testing for SARS-CoV-2**...now that point-of-care fingerstick tests are entering the scene.

These serology tests aim to identify a RECENT or PRIOR infection with COVID-19...and many patients are curious if they've had it.

The *Assure/FaStep COVID-19 IgG/IgM* antibody test is the first to have an "emergency use authorization" (EUA) for use under a CLIA waiver...so it can be done in pharmacies without sending to a lab.

This test gives qualitative or "yes/no" results in about 15 minutes.

But educate about limitations of antibody testing. A positive test does NOT mean the patient's immune or protected from reinfection.

Explain that it's too soon to say how long antibodies to SARS-CoV-2 last. Early evidence suggests they can be detected about 2 weeks after symptoms start...peak at 3 to 4 weeks...and wane over time.

This means it probably doesn't make sense to test for antibodies if symptoms or exposure occurred months ago.

Also point out that while a negative antibody test means a patient has probably not recently had COVID-19, false positives are often a problem...even with tests reported to be highly sensitive and specific.

That's because the likelihood a patient with a positive test truly has antibodies...the test's positive predictive value (PPV)...depends on the prevalence of COVID-19 in a given area.

For example, *Assure/FaStep* is labeled as 100% sensitive and 98.8% specific. Plugging in a prevalence of 25%...the current estimate for some COVID-19 "hot spots"...results in a PPV of about 97%.

But prevalence is currently below 5% in MOST areas of the United States...making PPV about 80% at best. This means at least 1 in 5 patients who test positive may not actually have antibodies.

Check your health dept website for estimates of local prevalence.

Continue to emphasize physical distancing, handwashing, and mask-wearing...even if patients have a positive antibody test.

Find out more about rapid testing options, including diagnostic tests, in our *COVID-19 Point-of-Care Testing* chart. Use our chart, *COVID-19 Testing FAQs*, to interpret and explain results.

## Key References:

- [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-point-care-antibody-test-covid-19](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-point-care-antibody-test-covid-19) (10-19-20)
- [www.idsociety.org/practice-guideline/covid-19-guideline-serology/](https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/) (10-19-20)
- [www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html) (10-19-20)
- [www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance) (10-19-20)

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