

Understand COVID-19 Tests and How to Interpret Results

Questions will continue to pop up about **diagnostic and antibody tests for SARS-CoV-2**...as more people are tested for COVID-19.

Diagnostic tests use a respiratory sample to help identify ACTIVE infection with COVID-19...and include molecular or antigen tests.

Expect to test patients exposed to COVID-19 or with symptoms...those who will undergo elective surgery...and possibly any patient being discharged to a long-term care facility.

Most hospitals use molecular, or PCR, tests. These look for RNA from SARS-CoV-2. Some of these tests give quick results...but many can take a day or more, especially if using a send-out lab.

Be aware, FDA generally grants an "emergency use authorization" (EUA) when molecular tests are at least 95% sensitive and 100% specific.

On the other hand, antigen tests detect bits of viral proteins from SARS-CoV-2. They're fast and inexpensive...but may be only 80% sensitive, making them less useful to rule out COVID-19.

Keep in mind, false negatives can occur. Nasopharyngeal swabs can be hard to obtain...and viral loads can be low early in the illness.

If a symptomatic patient tests negative, consider retesting with a molecular test...especially if the first test was an antigen test.

But don't retest to see if the virus has cleared...since patients can remain positive for weeks.

Antibody tests use a fingerstick or venipuncture blood sample to help identify a RECENT or PRIOR infection. These tests should be at least 90% sensitive and 95% specific to get an EUA.

A negative test means a patient has probably NOT had COVID-19.

But a positive test doesn't mean the patient's immune...or even that they've had COVID-19, due to false positives.

That's because positive predictive value...the likelihood a patient with a positive test result truly has antibodies...is low when overall disease prevalence is low, no matter how good the test is.

And explain that right now, there's no area in the U.S. where COVID-19 is common enough to make positive predictive value much over 50%.

Don't expect to use antibody tests in the hospital for now.

See our chart, *COVID-19 Testing FAQs*, for a deeper dive into who to test, respiratory sampling methods, and interpreting results.

Key References:

- www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas (6-26-20)
- www.covid19treatmentguidelines.nih.gov/overview/sars-cov-2-testing/ (6-26-20)
- www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf (6-26-20)

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- www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics (6-26-20)
- www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html (6-26-20)
- JAMA 2020;323(22):2249-51

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