YOUR TOP 3 COVID-19 QUESTIONS, ANSWERED

What are the different types of tests and the use cases for each?

Below we break down the four major types of Covid-19 tests and examples of use cases for which they are most suited.

Test type	Description	Suggested use cases
Lab-processed PCR[1] tests	These tests are used to diagnose individuals currently infected with Covid-19 by amplifying the viral genetic material. Many diagnostics companies have designed their test kits to be able to be run on multiple large-scale processing machines to improve throughput. However, it typically takes at least a few days to receive results – and may be even longer if there is a test processing backlog as we saw early in the outbreak.	• High-volume testing for symptomatic individuals, such as in certain inpatient and low-acuity outpatient settings • Asymptomatic individuals who have come into contact with someone known to be infected with Covid-19 • Patients who have an upcoming elective procedure or hospital stay
Point-of-care PCR tests	Like lab-processed PCR tests, point-of care tests are used to diagnose individuals with active Covid-19 infections. Points-of-care tests offer the benefit of near-immediate turnaround times – as low as 5-15 minutes. However, because they require special onsite processing technology, point-of-care tests are significantly lower-throughput than lab-processed tests. As a result, they are not ideal for testing a large number individuals simultaneously.	• Highly acute/urgent patients in hospital settings such as intensive care, emergency department, operating room, or labor & delivery, to inform the level of safety precautions required as well as course of treatment • Urgent care centers – because of the low throughput, criteria should be in place around what types of patients (e.g., patients with the highest index of suspicion) should receive the test • Patients/residents and staff at post-acute or long-term care facilities – due to high risk levels and logistical barriers to testing • Suspected cases among workers in essential occupations frequently in contact with the public (including frontline health care workers)
Antigen tests	Similar to PCR tests, antigen tests are used to identify active Covid-19 infections–but rather than amplifying viral genetic material, antigen tests look for viral proteins. They can be turned around in a matter of minutes, but because the test methodology offers lower sensitivity than PCR, they carry a higher risk of delivering false negative results. Given that, negative results in symptomatic/probable cases should be confirmed with a PCR test.	• Screening individuals for potential infections in situations in which it is important to quickly ascertain whether Covid-19 may be spreading, such as: frontline health care workers, staff and residents in congregate care settings, other essential workers, and certain workplaces in which large groups are working in close proximity to one another • Epidemiological studies to monitor relative infection rates over time
Serological (antibody) tests	Antibody tests are used to identify individuals with signs of past (rather than current) infection. Compared to other tests, the threat of a false positive is relatively high, and not enough is presently known about whether recovering from the virus actually confers immunity to act on positive results.	• Antibody tests are best used as epidemiological tools to understand the extent of population spread and fatality rates, not as diagnostic tools to identify active cases

1. Polymerase chain reaction

What evidence is available on the accuracy of Covid-19 tests?

Generally speaking, **PCR tests** for Covid-19 are considered the most accurate type of test available at this time. Unfortunately, performance characteristics for individual Covid-19 PCR tests have not been aggregated to conduct an industry-level analysis of test specificity or sensitivity. However, as a part of securing FDA[1] approval, vendors provide analytical sensitivity, inclusivity, specificity, and clinical evaluation data in each test's application for Emergency Use Authorization (EUA). The FDA maintains a list of tests that have received EUAs with links to either the Instructions for Use or an "EUA Summary," either of which will contain the test's validation data.[2]

Antigen tests have high specificity—meaning that a positive result can be considered highly accurate—but lower sensitivity than PCR, so they run a greater risk of returning false negative results. The first antigen test was authorized by FDA for use on May 8, making it the newest type of test on the market. As a result, there is relatively little data available about its accuracy in the field at this point.

Due to ongoing reports of inaccurate **serology (antibody) tests**, FDA is overseeing federal evaluation of all antibody tests that have received EUA. Among the first twelve tests evaluated, they found:

- Sensitivity ranging from 88-100%

- Specificity ranging from 94.4-100%

- Positive predictive value ranging from 46.8-100%

- Negative predictive value ranging from 99.4%

Some tests showed variability across ability to detect IgG and IgM antibodies. An earlier study of hospitalized patients conducted by researchers from academic medical institutions similarly found heterogeneous assay performance among SARS-CoV-2 antibody tests. In both evaluations, most tests had a specificity above 95% (most above 99% per federal evaluation). The earlier study found that tests were more accurate as time wore on (e.g., 16-20 days post symptom onset and >20 days post symptom onset).

1. Food and Drug Administration
2. For example, performance characteristics of Abbott's RealTime SARS-CoV-2 test are found on pages 11-13 of their Instructions for Use available here.

How much testing does the United States really need?

Extensive testing is required to identify new cases of Covid-19 and prevent community spread by isolating confirmed patients and those at risk of infection due to contact with confirmed cases. It is especially important to provide access to on-demand testing for individuals in essential roles who, if infected, could pose a risk to others, such as health care workers and nursing home staff.

Experts present varying views of how much testing is required to safely reopen society and keep it open:

Public health expert projections for the rate of **diagnostic testing** required have ranged from 2.27–5.88 tests per 1,000 population per day. The federal government has stated that each state should plan to test a minimum of 2% of its population every month beginning in May; individual state targets range from 2% to 14.9% per month. Per the White House Covid-19 Strategic Testing Plan, states are responsible for setting and reaching their own testing targets, and should adjust geographical target testing rates based on test positivity rates, population vulnerability, extent of concurrent mitigation strategies, (e.g., social distancing) in the region, and resource capacity.

> Expert projections for diagnostic testing rates are based primarily on PCR tests. Experts have not yet issued recommendations around the number of antigen tests that will be required; however, they hold promise as a potential solution for monitoring population infection rates at scale over time. According to FDA, antigen tests "can generally be produced at a lower cost than PCR tests and once multiple manufacturers enter the market, can potentially scale to test millions of Americans per day due to their simpler design."

Experts have not issued targeted recommendations around the number of **serological (antibody) tests** that will be required. If presence of antibodies is found to correlate to lasting immunity, experts advocate deploying antibody tests to the same extent as diagnostic tests. In the meantime, we have seen antibody testing deployed at scale for targeted populations or for specific public health research purposes (for example, testing an entire health system's workforce or a sample of residents in a defined geography).