

Will the new 15-minute COVID-19 test solve US testing problems?

September 2 2020, by Zoë McLaren



The Abbott BinaxNOW rapid antigen test claims to give results in 15 minutes.
Credit: [Abbott](#)

On Aug. 26, the [Food and Drug Administration](#) granted an [Emergency](#)

[Use Authorization](#) to a new rapid antigen test for COVID-19 called the [BinaxNOW test](#).

I [study public health policy](#) to combat infectious disease epidemics. Testing is one of the most powerful tools available to fight the spread of COVID-19. The [new test](#) is [inexpensive, rapid and easy to use](#). It will [massively scale up](#) access to testing, but hurdles remain in achieving widespread, frequent COVID-19 testing.

What type of test is BinaxNOW?

The credit-card-sized test is an [antigen test](#) that detects a [specific viral protein](#) from SARS-CoV-2. It [costs US\\$5](#) and doesn't require a lab or a machine for processing.

Performing the test is simple. A health care worker or technician would use a swab to collect a sample from [less than 1 inch inside the nostril](#). They would then combine the sample with a [few drops of chemicals](#) inside the test card. Within 15 minutes, the test strip would show a positive or negative result. The [test is also paired with an app](#) that produces a digital code that can be scanned to show proof of a recent negative COVID-19 test.

What does the Emergency Use Authorization allow for?

The BinaxNOW test is currently only authorized for patients who have had [COVID-19 symptoms for seven days or less](#), which is when virus levels in the body are [likely to be high](#). It must be [prescribed by a physician and performed by a trained technician](#) or other health care worker.

The PCR test for COVID-19 is currently widely used and considered the gold standard, but requires patient samples to be sent to a lab and can take days to provide results. The new antigen test is designed to be a [cheap and quick alternative to PCR testing](#) for diagnostic purposes in a medical setting. It would add critical capacity to an overstretched testing system.

The emergency use authorization provides [preliminary authorization](#) for doctors to prescribe the antigen test while the full FDA approval process is ongoing. The authorization could be [revoked](#) if the test is not as accurate or reliable as expected.

How accurate is this test?

[Abbott, the health technology company](#) that produces the test, reports that when patients had symptoms the test was in agreement with PCR testing for [97.1% for COVID-19 positive cases and 98.5% for COVID-19 negative cases](#). This is [high enough for diagnostic settings](#) where accuracy is critical.

However, the true accuracy could be lower because the [performance testing group was only 102 people](#) and the accuracy hasn't been validated by the FDA as part of the full approval process. There will inevitably be some [false negatives](#) and false positives with the BinaxNOW test since accuracy isn't 100%, but the [FDA will monitor the data](#) to make sure the test meets the reported accuracy.

Can this test be used for widespread screening?

The BinaxNOW test is cheap, rapid, able to be mass-produced and easy to use outside a lab. This makes it a promising candidate for widespread screening. However, the test is currently only authorized for people with

COVID-19 symptoms.

This is an obstacle because an estimated 40% of all COVID-19 cases are asymptomatic and these people likely don't know that they're contagious. To maximize the effectiveness of any COVID-19 screening program, it is important to test people whether they have symptoms or not.

Health care providers are able to prescribe the BinaxNOW test for asymptomatic patients for [off-label use](#), but health officials [don't yet know how accurate the test is](#) when performed on asymptomatic people.

Is this test a game-changer?

The massive expansion of testing access made possible by the BinaxNOW test will almost surely outweigh the downsides of a small number of inaccurate results. Abbott plans to manufacture [50 million tests per month](#) starting in October. This will quickly exceed the [76 million COVID-19 tests](#) the U.S. has performed over the last six months.

Widespread, frequent testing is [effective at slowing the spread](#) of the [coronavirus](#). The new testing capacity made possible by the authorization of this rapid antigen [test](#) represents a major advance in bringing the pandemic under control.

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