FDA Approves $5 COVID-19 Test That Gives Results in 15 Minutes

A new COVID-19 test will cost just $5. Getty Images

- The FDA has given emergency approval to a new COVID-19 test that can give results in 15 minutes.
- The test is not as accurate as PCR tests that can take days to get a result.
- Experts say more tests may help us get a handle on the COVID-19 pandemic.

All data and statistics are based on publicly available data at the time of publication. Some information may be out of date. Visit our coronavirus hub and follow our live updates page for the most recent information on the COVID-19 pandemic.

This week, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for a new COVID-19 test that allows results to be read directly by healthcare providers.

“This new COVID-19 antigen test is an important addition to available tests because the results can be read in minutes, right off the testing card,” said Dr. Jeff Shuren

Trusted Source

, JD, director of the FDA’s Center for Devices and Radiological Health in a statement

Trusted Source

.

He explained that this would allow people to know if they’re infected, “in almost real-time.”

Results in 15 minutes

According to a press release from Abbott, the company that created the new test, it’s highly portable, affordable, can provide results in 15 minutes, and only costs $5s per test.

“The thinking until more recently has been a push to have more accurate tests available. But as such tests continue to be fraught with delays related to availability of supplies including swabs and reagents, we are concerned

that ongoing delays have led to missed cases and more people getting infected," Dr. Robert Glatter, emergency physician at Lenox Hill Hospital in New York, told [name removed].

The new test is called the BinaxNOW COVID-19 Ag Card

Trusted Source

. It is an antigen test that looks for pieces of viral material in samples. These tests aren't as accurate as polymerase chain reaction (PCR) tests that look for the genetic material of the virus.

Abbott emphasized that the device will be "an important tool to manage risk by quickly identifying infectious people so they don't spread the disease to others."

According to the FDA

Trusted Source

, the testing process is simple.

A healthcare provider swabs the patient's nose and places the sample on a test card containing a testing reagent. About 15 minutes later, the provider

reads the results from the testing card. Similar to some pregnancy tests, results are indicated by the number of lines.

Two lines indicate COVID-19 infection, while one line is a negative result.

Free app serves as digital health pass

According to Abbott, BinaxNOW can be linked with a free, first-of-its-kind app called NAVICA, compatible with iPhone and Android devices.

It will allow people who test negative to show a temporary digital health pass that has the date of your test and is renewed every time you're tested at a NAVICA-enabled test center.

The results are encrypted, and you decide with whom you choose to share them.

For those who test negative, the app will display a temporary encrypted digital pass with a QR code, similar to an airline boarding-pass. If you test positive, you'll receive a message in the app to quarantine and talk to your doctor.

According to Abbott, organizations can view and verify your infection status on a mobile device to facilitate entry into their facilities and should be used

in addition to precautions like handwashing, social distancing, and mask wearing.

Test is fast, but not as accurate

A concern is that the rapid test isn't as sensitive as those that can take days to process.

"The new Abbott test is a rapid antigen test [administered via nasal swab] that looks for the presence of viral parts or proteins, as opposed to specific genetic material," said Glatter. "As a result, its sensitivity is lower compared to a standard PCR nasal swab that is run in a lab."

Although there are more accurate saliva tests approved for use, Glatter emphasized that they still require the sample to be sent to a lab "with a prolonged turnaround time, still taking several days in some cases."

The FDA cautions

Trusted Source

that this reduced sensitivity means, "Negative results from an antigen test may need to be confirmed with a molecular test prior to making treatment decisions."

Rapid and slow testing work together

In a recent interview, National Institute of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony Fauci pointed out, “The issue with surveillance is namely rapid testing or testing on the spot, whether you want to determine if you’re going to let students in a university into a dorm, or whether you want to let workers into a factory.”

Fauci emphasized that both kinds of tests, lab analyzed and rapid, serve critical roles in controlling the pandemic.

“We can have sort of two types of testing,” he said. “Those in which you very accurately want to know a person is infected so you can do the proper channeling of resources for contact tracing and others when you want to know a little bit more about what the level of infection is in the community.”

Glatter explained that more rapid and frequent testing — even if less accurate, could identify those people needing immediate treatment, “possibly helping to identify those at greatest risk of spreading the disease.” He added that an imperfect test is acceptable “in order to perform more of them in a shorter window of opportunity.”

On Thursday, President Donald Trump announced the purchase of 150 million rapid COVID-19 tests as part of a $750 million agreement with Abbott, reported CBS News.

Under this agreement, the Administration will acquire 150 million tests.

“This is a major development that will help our country to remain open, get Americans back to work, and kids back to school,” White House Strategic Communications Director Alyssa Farah said in a statement reported by CBS News.

The bottom line

The FDA has issued an emergency use authorization for Abbott’s rapid COVID-19 test. It’s inexpensive, and results can be read within minutes. However, it’s not as accurate as tests sent to a lab.

Experts say this isn’t a problem because both kinds of tests help control the pandemic.

They also say rapid testing, even if not as accurate, can help identify people at greatest risk for spreading the disease as quickly as possible.