## FDA Approves 5-Minute Diagnostics Test for COVID-19

The molecular diagnostics test is the fastest test for the novel coronavirus in the U.S. Faith Ryan

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The Food and Drug Administration Friday issued an emergency use authorization for a point-of-care, molecular diagnostics test for COVID-19 that delivers positive results in five minutes and negative results in 13 minutes.

The medical-tech company that created the test, Abbott Laboratories, will deploy 50,000 tests a day in the U.S. starting April 1. They will be sent to areas that need them the most, such as hospital emergency rooms and urgent-care settings.

The novel coronavirus test runs on Abbott's ID NOW Molecular Platform, the most common point-of-care platform for the flu, strep throat and other respiratory infections testing in the U.S. The test is about the size of a small toaster and provides a high level of accuracy crucial for determining whether someone is infected with the virus.

Abbott's m2000 RealTime System, another coronavirus testing device, had also launched last week after gaining FDA approval. The test takes more time to produce results but can be used in hospitals and laboratories to issue around one-million tests per week. Combined, these efforts would provide an estimated total of 5 million tests per month.

"The COVID-19 pandemic will be fought on multiple fronts, and a portable molecular test that offers results in minutes adds to the broad range of diagnostic solutions needed to combat this virus," said Abbott President and COO Robert Ford in <u>a press</u> release.

Currently, testing is the biggest challenge that the U.S. faces, with the country unable to handle the capacity for the amount of testing needed to be done quickly at a large scale. Many COVID-19 tests take about a week to produce results.

Along with other fast, advanced testing working through FDA's testing-approval pipeline, these efforts will support successful identification and testing for those infected, which <u>health experts say is critical</u> to each country's virus-control response.

"Right now, having access to tests that can give results quickly & accurately is pivotal in diagnosing #COVID19 & helping to #SlowTheSpread," FDA Commissioner Stephen Hahn tweeted. "FDA's EUA for Abbott's point of care diagnostic will help to get more rapid tests to medical professionals and patients who need them now."

The second fastest test result system to date for COVID-19 is Cepheid's <u>45-minute</u> <u>SARS-CoV-2 test</u>, which the FDA also approved via <u>emergency use authorization</u>.

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