FDA Approves 45-Minute Point-of-Care COVID-19 Diagnostic Test

The solution automates and integrates sample prep, nucleic acid extraction and detection for fast results.

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The Food and Drug Administration issued emergency-use authorization to a new rapid point-of-care COVID-19 testing solution from Silicon Valley that can detect the novel coronavirus in 45 minutes.
Molecular diagnostic testing Cepheid’s Xpert Xpress SARS-CoV-2 can test more quickly than other approved testing devices in the U.S. so far. The solution can operate on any of Cepheid’s 23,000-plus automated GeneXpert Instrument Systems worldwide, the company said in an announcement Saturday. 5,000 of those systems are already deployed across the U.S. for point-of-care testing and hospital use.

The solution is one of a few other COVID-19 testing solutions for which FDA has granted emergency-use authorizations, but Cepheid’s is faster and one of the first for point-of-care use.

Other tests have been laborious and time intensive because providers would have to swab the back of patients’ noses for samples to send to commercial, hospital or public health clinics, or to the Centers for Disease Control and Prevention for processing that can take up to several days.

While the new solution still involves taking a nasal swab, providers can conduct the test and diagnosis in the office or clinic within the same hour, expediting the testing process.

“Today marks an important step in expanding the availability of testing and, importantly, rapid results,” FDA Commissioner Stephen Hahn said. “Point-of-care testing means that results are delivered to patients in the patient care settings, like hospitals, urgent care centers and emergency rooms, instead of samples being sent to a laboratory. With today’s authorization, there is now an option for testing at the point of care, which enables patient access to more immediate results.”

The new solution can ease the burden that providers are increasingly experiencing as the demand for COVID-19 testing and treatment increases nationally.

“During this time of increased demand for hospital services, clinicians urgently need an on-demand diagnostic test for real-time management of patients being evaluated for admission to healthcare facilities,” Cepheid Chief Medical and Technology Officer Dr. David Persing said. “An accurate test delivered close to the patient can be transformative — and help alleviate the pressure that the emergence of the 2019-nCoV outbreak has put on healthcare facilities that need to properly allocate their respiratory isolation resources.”
Cepheid leveraged the design principles of its current Xpert Xpress Flue/RSV cartridge technology to provide rapid detection of current — and even future — variants of SARS-CoV-2. The company used the preexisting cartridge technology to target multiple regions of the viral genome and provide quick lab results.

Persing said that since conditions such as pneumonia and sepsis stem from COVID-19, but also from other bacterial and viral infections. He said that rapidly differentiating COVID-19 cases from other infections can help better allocate medical resources and treatment services.

“The results are available much more quickly, and that means that the results will play into how those patients are managed — who gets respiratory isolation, who needs antibiotics, who doesn’t need antibiotics?” Persing said. “Those kinds of decisions can be made in real time.”

Cepheid’s test will be ready for shipment before the end of the month.

"The test we’re authorizing today will be able to provide Americans with results within hours, rather than days like the existing tests, and the company plans to roll it out by March 30, which is an incredibly rapid timeline for such an effort," Department of Health and Human Services Secretary Alex Azar said in a press release. "With new tools like point-of-care diagnostics, we are moving into a new phase of testing, where tests will be much more easily accessible to Americans who need them."