



Diagnostics

Companies are racing to develop COVID-19 tests for the US. Will they help?

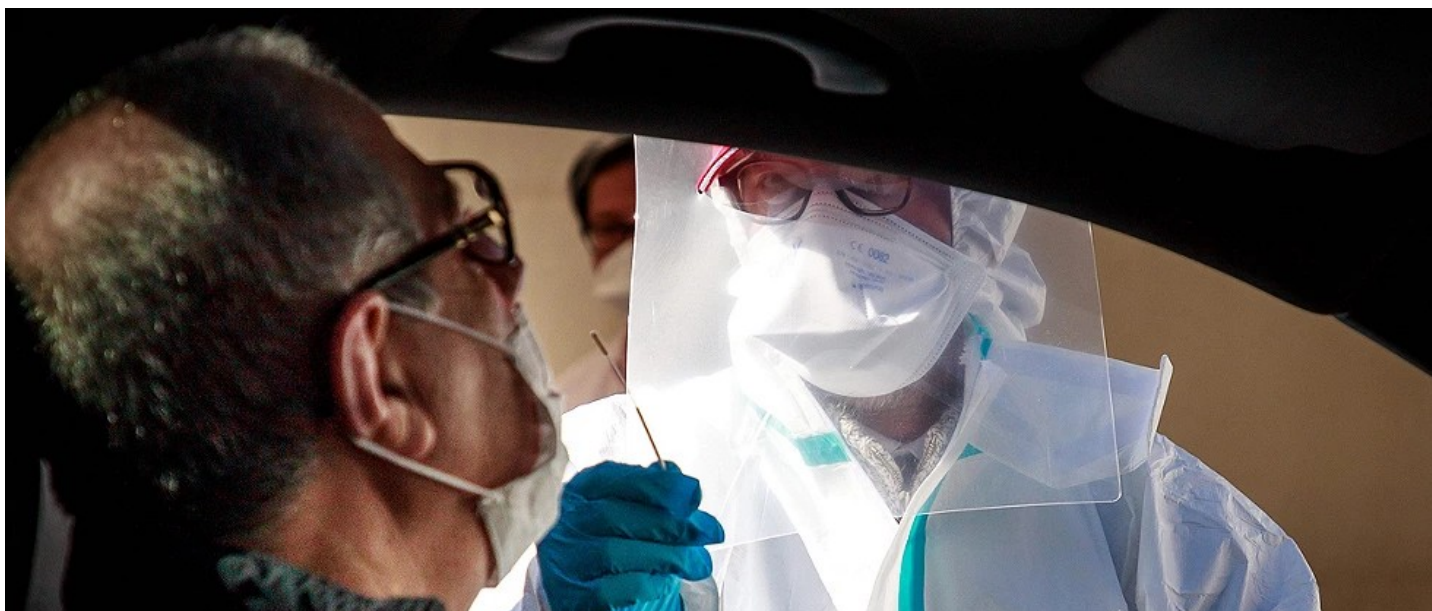
With a diagnostic backlog hampering disease control efforts, scientists are turning to CRISPR and other technologies to bridge the gap

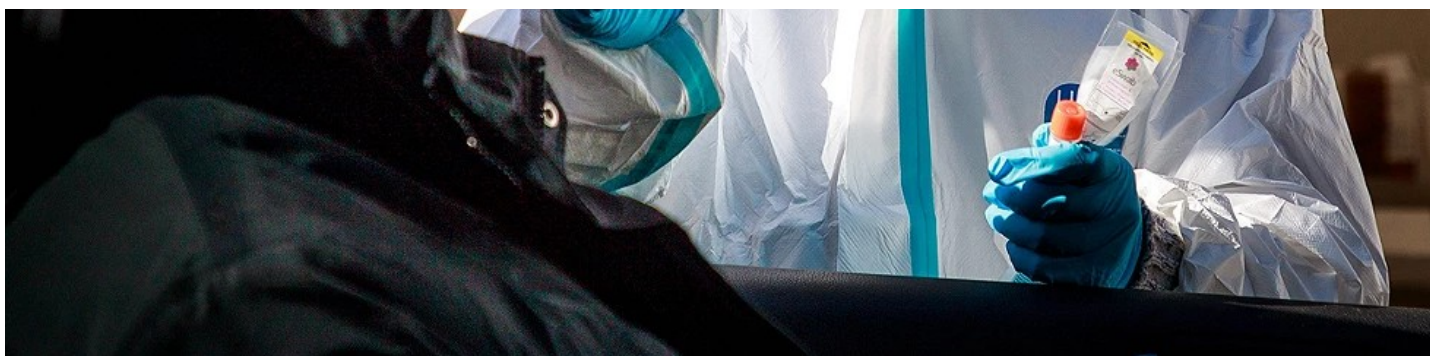
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SAVE





As the US tries to break the logjam of COVID-19 testing with more tests and different technologies, some places have turned to drive-through testing to gather samples. |

Credit: Newscom

While countries like Germany and South Korea have flattened the curve of the COVID-19 pandemic through widespread testing, the US has seen cases surge. Many blame that meteoric rise, in part, on bottlenecks in diagnosing the novel coronavirus. To try to break this logjam, some companies and academic groups are developing tests that exploit a variety of technologies and platforms.

COVER STORY

Companies are racing to develop COVID-19 tests for the US. Will they help?

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What's not clear is how long it will take to get these technologies to the people who need them or if they will do much to break through the backlog. Despite the availability of [vast numbers](#) of diagnostic tests developed early in the pandemic for use in China and elsewhere, large pharmaceutical companies and universities were able to jump into action in the US only after a federally produced diagnostic kit [ran into trouble](#) earlier this year, limiting its deployment.

And worldwide [shortages of critical supplies](#) needed to run these tests have hampered their widespread use. Early on, some smaller test makers had been unable to meet the [crush of requests](#) for their homegrown tests. The guidelines for who should be tested have changed several times since the first cases of COVID-19 were diagnosed. Even those who can get tested must often wait days, if not longer, for an accurate diagnosis.

“It’s becoming more scary and more dire, specifically with our inability to get diagnostics deployed at the rate of what we need to actually control the infection,” says Janice Chen, the chief technology officer of Mammoth Biosciences, a company using the CRISPR gene-editing system to develop a SARS-CoV-2 diagnostic. “It’s become so incredibly clear that diagnostics are critical to address something like a global pandemic.”

Some public health officials say that we have [lost our chance](#) to contain the disease. As of April 8, nearly 400,000 Americans have been diagnosed with COVID-19. Experts have said the actual number of people with the disease is up to 10 times that amount.

Meanwhile, both companies and academic labs continue to churn out COVID-19 tests that are based almost entirely on a method called polymerase chain reaction, or PCR, which detects small amounts of viral RNA. In this assay, probes, often labeled with fluorescent molecules, sniff around for coronavirus genetic material from a human nasal swab. If the sample contains any viral RNA, enzymes convert that RNA to DNA and copy the DNA many times through a series of heating and cooling reactions. That now-abundant genetic material can be detected many ways, but most often through the growing fluorescent signal given off as the genetic material gets copied. This is all done in machines that control the temperatures of the reactions and read the fluorescence of the samples.

The tests can take a couple of hours, not counting the time to transport samples and then wait for machines to be freed up. These logistical issues, coupled with shortages of nasal swabs and solutions that are required for the tests to be done, have hampered even further what many consider an already-slow response to the burgeoning pandemic.

These speed bumps are some of the reasons why many industry watchers and public health officials are praising the development of a 5 min bedside, or point-of-care, test [produced by Abbott Laboratories](#). Approved in late March, the test relies on PCR but uses a different method of copying genetic material, allowing it to be done at a constant temperature and quickly.

Other companies that use this method, called [isothermal amplification](#), for infectious disease diagnostics have developed specialized enzymes that can copy viral RNA without the temperature cycling used in more traditional PCR. It’s not clear exactly how Abbott is employing isothermal amplification, but the company says the test can be done in a small, portable machine that many hospitals already use to diagnose other infectious diseases. Abbott says this test and another, more traditional PCR diagnostic it developed can perform up to [5](#)

[million COVID-19 tests per month](#) total.

Other companies are also trying to tweak the PCR-based tests to make them faster and easier to do. For example, Cepheid's COVID-19 detection assay was the [first approved](#) point-of-care diagnostic in the US. Like in the Abbott test, patient samples can be run in machines many hospitals already have. But instead of requiring nasal swabs, which are in short supply, the Cepheid bedside test can use saline washes.

Companies are working on other technologies to swiftly determine who has been infected by the coronavirus. The most urgent calls are for widespread use of serological assays—blood tests that can detect the presence of viral proteins or how our immune systems are responding to disease. A few days after an infection takes hold, our immune systems try to fight it by releasing antibodies that recognize viral proteins as invaders. After helping kill cells that the pathogen has wormed itself into, those antibodies linger in the bloodstream.

Serological tests would look for those antibodies, allowing health-care workers to diagnose not only current infections but also past infections, giving disease trackers a strong sense of how pervasive this pandemic has been and who really is at risk for infection.

CTK Biotech, a diagnostic company based in Southern California with several types of SARS-CoV-2 tests in use in China, is developing an antibody test for coronavirus infection for the US market. Vasco Liberal, a director at the company, says it is nearly done validating it, using patient samples from hospitals in China. CTK will be applying for the US Food and Drug Administration's emergency use authorization in a few weeks, Liberal says. This is a regulatory mechanism that would allow the test—already in use outside the US—to be used during the pandemic in the US.

From a tube of blood, [CTK's test](#) can detect two types of SARS-CoV-2-specific human antibodies: one, called IgM, that corresponds to the early response to infection and one, called IgG, that gets produced a little later. Liberal compares the assay to a pregnancy test in that it gives a color-based readout from a small drop of blood deposited onto a strip that is built into a small cassette. If the sample contains antibodies to SARS-CoV-2, a reddish band will appear. The test can be performed in the hospital and takes as little as 15 min once the blood has been collected. Similar to tests developed in China, it requires less expertise to perform than nucleic acid tests, according to company documentation.

These PCR-based assays and serological tests use technology that has been around for a while.

Several groups are applying newer technologies to stem the testing backlog. Perhaps the most prominent is CRISPR. The CRISPR-Cas system is a bacterial defense mechanism that chops up invasive genetic material. [Scientists have developed CRISPR-Cas into a powerful gene-editing system](#), one that can make precise changes in DNA or RNA that it recognizes using a guide RNA that steers it to a specific spot in DNA or RNA.

Developing a CRISPR-based coronavirus diagnostic takes advantage of both the homing signal and the chopping activity of the system, Mammoth's Chen says. Mammoth is based in the Bay Area, which has been under a shelter-in-place order since March 16. Having the pandemic on its doorstep is one of the reasons why Mammoth has opted to divert some of its capacity to developing a coronavirus test, Chen says.

"In the early days, it was frankly very unclear how much of an impact coronavirus would have on the world," Chen says, describing conversations near the beginning of the year between company officials and one of its scientific advisory board members, who had been tracking the disease in China and had access to patient samples in the US. "It's turned into a very strong mission for the team to be able to provide a solution in such a time of need."

The company's test uses guide RNAs that match coronavirus RNAs. These guide RNAs, the Cas enzyme, and DNA that is coupled to a fluorescent molecule are added to a patient sample. If SARS-CoV-2 RNA is present in the sample, the guide RNA steers it to the Cas enzyme, which chops up both the viral RNA as well as DNA that is coupled to two things: a fluorescent molecule and a molecule that blocks its ability to fluoresce. When the DNA strand is cut, the quenching molecule is released, and the strand fluoresces, giving off a signal that is read by a machine that Mammoth has designed as part of its diagnostic platform.

Chen says that in laboratory testing, the company's CRISPR test can give results in about 30 min and that it can do 384 tests at once. But she acknowledges that field testing might show that the test takes longer. CRISPR-based tests might also suffer from the same shortages of supplies—be they nasal swabs or sample-preparation solutions—that have plagued the PCR-based tests, she says. Mammoth is currently validating its test on patient samples, including some from people who were on cruise ships with coronavirus outbreaks. As a way to get around the shortages, it is trying to develop its test for hospital-bedside use and eventual at-home use, which could involve different materials. Although several companies are touting tests that can be taken at home, the FDA has said that [none have been authorized](#).

Sherlock Biosciences and Broad Institute of MIT and Harvard are working together to develop their own CRISPR-based test. It involves a PCR step to amplify the amount of viral RNA in a patient sample. Then, the CRISPR system is added, and the mix is placed on a dipstick. If the sample contains viral RNA, the stick shows two lines corresponding to two SARS-CoV-2 genes. It has not yet been validated on patient samples, according to documentation released by the team working on the test. And a company called Cardea Bio is looking for partnerships to develop its bedside CRISPR test that reads out via a graphene-based electrical biosensor.

While companies work to make more testing available in the US, several prominent health experts have pointed to other countries as models. In China, the biopharma industry was called in fairly early to start developing diagnostic tests. In South Korea, public health officials, remembering how quickly the MERS (Middle East respiratory syndrome) coronavirus swept the country in 2015, quickly deployed drive-through testing and other rapid diagnostics to stem the novel coronavirus. It's not clear how many Americans have been tested for SARS-CoV-2—the Centers for Disease Control and Prevention said in early March that it had stopped collating these numbers and refers instead to state numbers. The [COVID Tracking Project](#) estimates about 2 million people have been tested in the US as of April 8.

Meanwhile, the US effort remains decentralized, with some places offering drive-through testing, some places offering large testing centers, and others offering few people tests. The US has quickly overtaken the world in number of confirmed cases, and with the backlog of tests, the scientific community has called for help to perform the assays.

On March 30, former FDA commissioner Scott Gottlieb said on cable news that April will be a tough month in the US, as infections climb and limited resources are diverted to the critically ill. But as more diagnostics become available, he said, especially the point-of-care tests offered by companies like Cepheid and Abbott, community-based testing will start to improve, and the US will be more prepared for future waves of infection.

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