Coronavirus testing is starting to get better — but it has a long way to go

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Friday morning a ray of light cracked through the ominous cloud of the pandemic caused by the novel coronavirus: The Swiss health care giant Roche introduced a new test for the virus that could be run more efficiently and with less manpower

than existing diagnostics, potentially doubling the capacity in the U.S. to detect the virus.

But the news only emphasizes the degree to which one of the world's great technological powers, the leading country in generating new biotechnologies and medical advances, has stumbled to test patients when other nations, including most of Europe, China, and in particular South Korea, have been able to do so much more efficiently.

The technology behind the tests for detecting the virus, called the polymerase chain reaction or PCR, was invented in the U.S. in 1983. Advances in other approaches to detect viruses, such as antibodies or gene sequencing, were pioneered here, too. But the U.S. health care system has proven unable to test its own people for the virus, SARS-CoV-2, and the disease it causes, Covid-19. To date, the U.S. has seen 1,629 cases and 41 deaths, although those numbers may not reflect reality because of low testing rates.

"This is a wake-up call for diagnostic testing in the United States," said Michael Pellini, a longtime diagnostics company executive who is now a managing partner at Section 32, a venture capital firm. He said that it has become too difficult to get new tests approved and paid for by insurers. "No one has spent any time evaluating the diagnostic system. So here we are in a ridiculous bind."

The Roche test is good news because it represents one of the private sector's largest players attacking the coronavirus outbreak with full force, and because the Food and Drug Administration moved with the necessary speed on clearance. That's in contrast to the federal government's response so far.

Roche's new diagnostic runs the PCR test for the virus on an automated system called cobas 6800/8800 (the numbers refer to a smaller and larger system). Paul Brown, head of Roche Molecular Solutions in Pleasanton, Calif., said that the company believes it can ship 400,000 of the tests this weekend from its Nutley, N.J., manufacturing facilities to laboratories already identified by the Centers for Disease Control and Prevention to do coronavirus testing.

Roche’s cobas 8800 system*ROCHE*

The U.S. currently has the capacity to run just 175,000 tests a week, according to an effort run by former FDA Commissioner Scott Gottlieb at the American Enterprise Institute. Even if those additional tests come online all at once, patients may not be able to get them. Right now, some health departments have not tested even patients with fevers and chest pain who are testing negative for other viruses. Efforts like drive-through testing centers, which were pioneered in South Korea and are now being launched by both New York state and developed by Trump administration in partnership with private industry, as announced today, could certainly help.

But every patient who has symptoms may need a test, and that will require even greater diagnostic capacity. Right now, the process is slow, with laboratories often taking several days to get back to doctors and patients. Thousands of tests came online this week from companies like Quest Diagnostics and LabCorp, but capacity has still lagged behind early promises — and the public health need.

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The Roche case offers some encouragement: Brown said that the company started working on its new test last month, and finished the work in six weeks. Roche asked the FDA for emergency clearance earlier this week and received it around

the stroke of midnight Friday. As he announced a national emergency Friday afternoon, President Trump promised that testing capacity would eventually reach 5 million.

Testing serves two purposes. It can tell whether an individual person is sick. But it also acts as our way of knowing how bad the epidemic is, and where it is worst. Other types of technologies might help with the second part, if not the first. Blood tests that look to see if people have antibodies for SARS-CoV-2 –when they become available — can tell us how many people have had Covid-19. Next-generation DNA sequencing technologies could also play a role in monitoring it.

Through all this, the CDC and other health officials now need to follow an old maxim: Don’t let the perfect be the enemy of the good.

Regulatory standards are important, and if the U.S. had organized its response sooner, getting the developers of diagnostic tests and major labs ready, there would have been time for an orderly process. But this is an emergency. And there is a need for speed.

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