

C.D.C. Labs Were Contaminated, Delaying Coronavirus Testing, Officials Say

[nytimes.com/2020/04/18/health/cdc-coronavirus-lab-contamination-testing.html](https://www.nytimes.com/2020/04/18/health/cdc-coronavirus-lab-contamination-testing.html)

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Sloppy laboratory practices at the Centers for Disease Control and Prevention caused contamination that rendered the nation's first coronavirus tests ineffective, federal officials confirmed on Saturday.

Two of the three C.D.C. laboratories in Atlanta that created the coronavirus test kits violated their own manufacturing standards, resulting in the agency sending tests that did not work to nearly all of the 100 state and local public health labs, according to the Food and Drug Administration.

Early on, the F.D.A., which oversees laboratory tests, sent Dr. Timothy Stenzel, chief of in vitro diagnostics and radiological health, to the C.D.C. labs to assess the problem, several officials said. He found an astonishing lack of expertise in commercial manufacturing and learned that nobody was in charge of the entire process, they said.

Problems ranged from researchers entering and exiting the coronavirus laboratories without changing their coats, to test ingredients being assembled in the same room where researchers were working on positive coronavirus samples, officials said. Those practices made the tests sent to public health labs unusable because they were contaminated with the coronavirus, and produced some inconclusive results.

In a statement on Saturday, a spokeswoman for the F.D.A., Stephanie Caccamo, said, “C.D.C. did not manufacture its test consistent with its own protocol.”

The F.D.A. confirmed its conclusions late this week after several media outlets requested public disclosure of its inquiry, which assuredly is part of a larger federal investigation into the C.D.C. lab irregularities by the Department of Health and Human Services.

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Forced to suspend the launch of a nationwide detection program for the coronavirus for a month, the C.D.C. lost credibility as the nation’s leading public health agency and the country lost ground in ways that continue to haunt grieving families, the sick and the worried well from one state to the next.

To this day, the C.D.C.’s singular failure symbolizes how unprepared the federal government was in the early days to combat a fast-spreading outbreak of a new virus and it also highlights the glaring inability at the onset to establish a systematic testing policy that would have revealed the still unknown rates of infection in many regions of the country. The blunders are posing new problems as some states with few cases agitate to reopen and others remain in virtual lockdown with cases and deaths still climbing.

While [President Trump](#) and other members of his administration assert almost daily that the U.S. testing capacity is greater than anywhere else in the world, many public health officials and epidemiologists have lamented the lack of consistent, reliable testing across the country that would reflect the true prevalence of the infection and perhaps enable a return to some semblance of normal life.

Dr. Robert R. Redfield, the director of the C.D.C., and other health experts have long suggested that contamination in the labs might have been the culprit. But even as several officials at the F.D.A. late this week cited contamination as the cause, a spokesman for the C.D.C., Benjamin Haynes, asserted that it was still just a possibility and that the agency was still awaiting the formal findings of H.H.S.

In a statement, however, he acknowledged that the agency’s quality control measures were insufficient during the coronavirus test development. Since then, he said, “C.D.C. implemented enhanced quality control to address the issue and will be assessing the issue moving forward.”

Initially, the C.D.C. was responsible for creating a coronavirus test that state and local public health agencies could use to diagnose Covid-19 in people, and then isolate them to prevent the spread of the disease.

“It was just tragic,” said Scott Becker, executive director of the Association of Public Health Laboratories. “All that time when we were sitting there waiting, I really felt like, here we were at one of the most critical junctures in public health history, and the biggest tool in our toolbox was missing.”

Mr. Becker said that public health laboratories started receiving the C.D.C. kits on Feb. 7, and by the next day members were already calling him to report that the test was not working accurately. He alerted both the C.D.C. and the F.D.A., which regulates medical devices, including laboratory tests.

“This is consistent with what we said was plausible when we found the problem at the beginning,” Mr. Becker said. “When we found the problem, it seemed to our community that it was a contamination issue that would cause a problem to this extent.”

The F.D.A. concluded that C.D.C. manufacturing issues were to blame and pushed the agency to shift production to an outside firm. That company, I.D.T., accelerated production of the C.D.C. test and says no more issues were reported.

Meanwhile, the F.D.A. also came under fire for not initially allowing commercial labs like Quest and LabCorp and others to begin ramping up production of their own tests.

More than two months later, nearly 700,000 Americans have become infected and close to 40,000 have died. Testing is still rationed in some states and uneven in others, and it can take days before doctors and patients receive results. Many infectious disease and public health experts say testing is nowhere near widespread enough to reopen the country or return to some semblance of normal.

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