

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

Fallout from the agency's failed rollout of national coronavirus kits two months ago continues to haunt U.S. efforts to combat the spread of the highly infectious virus.

By [Sheila Kaplan](#)

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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 Caccomo, said, "C.D.C. did not manufacture its test consistent with its own protocol."

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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.

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.

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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."

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