

The CDC works to overhaul lab operations after COVID test flop

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In early February 2020, Kirsten St. George and her team at New York state's public health lab received a test developed by the Centers for Disease Control and Prevention to diagnose people infected with the

new, rapidly spreading coronavirus.

But, like many labs around the country, it quickly found the test gave inaccurate results. So [test samples](#) had to be sent back to the CDC for processing, wasting time and leaving [state officials](#) "sort of blind to what the situation was with the disease," said St. George, chief of the laboratory of viral diseases at the Wadsworth Center, one of the nation's largest state public [health](#) labs.

"It was extremely unfortunate that it happened at such a critical time, in the early days of this emerging pandemic," she said.

An independent panel of laboratory researchers, public health and policy experts, and doctors say the CDC's flawed [diagnostic test](#) was one of the "most consequential" of the agency's pandemic missteps because it stymied national efforts to contain COVID-19 as the disease spread.

They blame the test's shortcomings on a series of problems rooted in how the CDC operated its laboratories: a lack of unified leadership for the labs developing the test; insufficient planning and quality control systems for producing tests for novel pathogens; and ineffective governance that sometimes placed clinical laboratory decisions in the hands of "non-laboratory experts" without diagnostic testing expertise.

The CDC says it's working to address its liabilities, using the findings of that advisory committee as a guide. It's a big job—one further complicated by new leadership at the agency, constrained resources, and continued antagonism and threatened budget cuts from members of Congress.

Failure to make sweeping changes could add to a growing lack of trust in the agency post-pandemic and threaten the nation's preparedness for the next public health threat.

"If the CDC can't change, their importance in health in the nation will decline," said Jill Taylor, a senior adviser for the Association of Public Health Laboratories. "The coordination of public health emergency responses in the nation will be worse off."

The CDC's original COVID test had two key problems, according to an internal analysis in 2021 by a group of agency staff. A design flaw and contamination during production at the CDC led the tests to give false positive results.

The work group that later performed an independent postmortem on the development of the test, using information provided by the CDC, came to the same conclusions.

"It was all surprising to me," said Joshua Sharfstein, a vice dean at the Johns Hopkins Bloomberg School of Public Health, who co-chaired the panel.

The panel concluded that these failures, fueled by problems within the agency, had human consequences.

"Lacking awareness of how rapidly and widely the virus was spreading, public health agencies were slow to recommend behavior changes or implement protective measures," its February report said.

A few short weeks after the flawed tests were released, life across the U.S. would grind to a halt, with officials resorting to mass lockdowns to slow the spread of the virus that has killed more than 1.1 million Americans.

The advisory group made 10 recommendations for how the CDC could prevent future failures when developing diagnostic tests, such as consolidating all lab operations into a new center with its own leadership,

separating research labs from those that develop clinical tests, and having independent, outside experts review tests made for pathogens with pandemic potential.

The agency began acting on some of those suggestions under the leadership of Rochelle Walensky, before she left her post as director in June, as part of the larger effort to overhaul the CDC. It instituted new agency-wide lab quality standards, started working to improve coordination with state labs, and established an internal review board to approve tests shared outside the CDC.

In July, Mandy Cohen took over as Walensky's successor. Cohen held top leadership positions at the Centers for Medicare & Medicaid Services during the Obama administration but not within the CDC. Already, she has run into headwinds from Republican members of Congress, who influence the agency's budget. Still, an agency spokesperson said these won't be major challenges.

"Improvements to further strengthen CDC's labs are well underway," said CDC spokesperson Kevin Griffis. "Reforms will continue to move ahead at full speed."

Other leaders within the agency said funding could prove a critical obstacle to instituting the recommended changes.

The agency is staring down a cut to one-time funding of more than \$1 billion in the wake of this summer's debt ceiling deal—more than one-tenth of its enacted core operating budget in fiscal year 2023. Republicans in the House are mulling legislation that would cut an additional \$1.6 billion in the upcoming fiscal year.

Recommendations for the agency to physically separate its clinical labs from its research labs or to train researchers to uphold new quality

standards will be heavy lifts because they require continuous funding, said Jim Pirkle, associate director for laboratory science and safety at the CDC.

"You can't get one bolus of money, and then say, 'OK, now that solves it till the end of time,'" he said. "The things that we're talking about are things that we have to sustain."

And money is only one piece of the puzzle, said the Association of Public Health Laboratories' Taylor, who also co-chaired the advisory group.

A culture change will also be required, she said, in which scientists inside the CDC see themselves as part of the larger U.S. laboratory community, subject to the same quality standards.

The advisory group looking at the COVID test development found clinical lab decisions were made "by experts in basic science research rather than by certified clinical laboratory professionals."

In addition, research and clinical work would happen in the same lab space, which made it hard to ensure quality standards for test development and "very easy to cut corners," Taylor said.

"CDC has considered itself a bit special and not necessarily needing to follow the rules like everyone else does, and that's a shame," Taylor said.

Taylor said failure to implement the work group's recommendations could force the CDC to cede ground to commercial lab companies in developing diagnostic tests for new disease threats.

While commercial labs can operate at larger scales than [public health](#) labs can, they are for-profit entities and motivated by the market.

In a recent article, leaders of the American Clinical Laboratory Association, an industry trade group, wrote that some lab companies delayed creating a COVID test until "clear signals that a testing market would materialize."

The CDC does that work without worrying about making money, said Anne Schuchat, former principal deputy director of the agency. In other words, they develop a test "because there's a new pathogen, and we need to know what's going on," she said.

As the COVID pandemic has shown, threats that might start small can quickly spread, take millions of lives, and cause years of global disruption.

Schuchat said the ability of the CDC to have the capacity to develop an accurate test to pinpoint novel pathogens and how they're spreading is critical.

"Our protection depends on it," she said.

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