After severe criticism of how the United States was handling coronavirus testing, the Food and Drug Administration announced at a press conference with President Donald Trump that it was changing

By **Jon Cohen** | Feb. 29, 2020 , 5:40 PM

The Food and Drug Administration (FDA) today **recommended a dramatic shift** in how it implements regulations that control whether laboratories can use diagnostic kits created in-house to test for infections of COVID-19. "We issued a policy this morning that allows us to have a lot of flexibility around the development of diagnostic tests," FDA Commissioner Stephen Hahn said at a White House briefing with President Donald Trump this afternoon. "We expect this policy to have a significant impact." The change could greatly expand the number of laboratories able to do coronavirus testing.

The U.S. government has come under **severe criticism** for not providing nearly enough tests needed to understand the extent of spread in the population. A test kit produced and distributed by the U.S. Centers for Disease Control and Prevention (CDC) was shelved after state and local labs trying it out discovered it contained a faulty reagent. As a result, many labs that have the capability to test themselves have not been allowed to do so.

The new recommendations focus on "high-complexity testing laboratories" that are certified under federal rules known as Clinical Laboratory Improvement Amendments. This group of facilities includes many hospital labs, like the one where epidemiologist Michael Mina works at Brigham and Women's Hospital. "Essentially it's opening up a clear

and concise avenue for labs like the one at Brigham and Women's," Mina says. "It's what I've been advocating for a month now."

If these labs want to make and use their own tests, FDA says, they should send five positive and five negative samples, as determined by their protocols, to another qualified lab for confirmation. FDA still requires labs to submit what's known as an emergency use authorization (EUA) application to the agency. "For a reasonable period of time after validation and while they are preparing their EUA requests, FDA does not intend to object to the use of these tests for specimen testing," the recommendations state.

"It's their method of saying just go ahead and start doing the testing, it's sort of got out of hand, and if you don't hear from us in a year, just keep testing," Mina says.

Scott Becker, CEO of the Association of Public Health Laboratories, praised the FDA decision in a statement. "We are greatly encouraged by expanding the testing capacity to the clinical laboratory community," Becker said.

Together with an earlier recent decision to change the recommended coronavirus testing protocol to steer around the reagent problem in CDC kits that were distributed to public health labs, Becker said, "These steps will jump-start testing and surveillance capabilities and greatly enhance our efforts to protect the health of individuals and communities across the country." He anticipates that public health labs will be able to run 10,000 tests a day by the end of next week.

At a CDC media teleconference today that described the first death from the virus in the country and a large cluster of potential cases at **a Washington state nursing home**, Nancy Messonnier, director of the Center for the National Center for Immunization and Respiratory Diseases, said new manufactured testing kits have been provided to the **International Reagent Resource**, a clearinghouse of sorts established by CDC. She said these kits can test 75,000 people. "With our enhanced surveillance and detection capacity, especially as more state and local public health labs come online, we expect to find more cases of novel coronavirus in the U.S.," Messonnier says.

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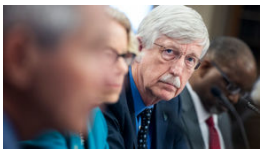

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GEOCHEMISTRY/GEOPHYSICS
The hunger forecast

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