

Coronavirus Test Kits Sent to States Are Flawed, C.D.C. Says

Some tests distributed by the agency deliver “inconclusive” readings. The C.D.C. will need to ship new ingredients, further delaying results.

By Denise Grady

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Some of the coronavirus testing kits sent to state laboratories around the country have flaws and do not work properly, the Centers for Disease Control and Prevention said on Wednesday.

The kits were meant to enable states to conduct their own testing and have results faster than they would by shipping samples to the C.D.C. in Atlanta. But the failure of the kits meant that states that encountered problems with the test should not use it, and would still have to depend on the C.D.C.’s central lab, which could cause several days’ delay in getting results.

“Obviously, a state wouldn’t want to be doing this test and using it to make clinical decisions if it isn’t working as well, as perfectly, at the state as it is at C.D.C.,” Dr. Nancy Messonnier, director of the National Center for Immunization and Respiratory Diseases, said at a news conference on Wednesday.

The C.D.C. recommends testing for people who have symptoms like fever, cough or shortness of breath, and who, within the past 14 days, have traveled to China or have been in close contact with someone who is infected with the coronavirus. Doctors with patients in that category are supposed to consult their state health department about whether the individuals should be tested for the virus.

The C.D.C. announced late Wednesday that another evacuee quarantined at a military base in California had tested positive for coronavirus. The latest individual who was diagnosed among the evacuees from Wuhan, the epicenter of the outbreak, brings the total of confirmed cases to 14 in the United States. A previous case was diagnosed at the Miramar base in San Diego on Sunday.

The first and second patients arrived on different planes and were housed in separate facilities at Miramar, according to the C.D.C. Dr. Chris Braden, an expert on the site, said in a statement that “At this time there is no indication of person-to-person spread of this virus at the quarantine facility, but C.D.C. will carry out a thorough contact investigation as part of its current response strategy to detect and contain any cases of infection with this virus.”

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The C.D.C. announced last week that it had begun shipping about 200 kits to laboratories in the United States and roughly 200 more to labs in more than 30 other countries. Each kit can test about 700 to 800 specimens from patients, the agency said.

Kits were shipped to every state, but officials did not say how many of the kits were faulty.

At a news conference on Wednesday morning, Dr. Messonnier said that test kits had been shipped to more than 30 other countries, but later in the day said that she was mistaken, and that the international shipments had been held back because of the flaw.

Before the kits were shipped to the states, Dr. Messonnier had emphasized repeatedly at news conferences that the kits would not go out until the C.D.C. was sure they were as accurate as possible.

Dr. Jeanne Marrazzo, director of the infectious diseases division at the University of Alabama at Birmingham, said accurate diagnostic tests were invaluable.

“The test is the only way you can definitely know you have the infection,” Dr. Marrazzo said. “You absolutely need it for case counting. It allows you to know who’s infected. You can treat those people, if a treatment is available, and you can isolate them.”

Doctors in China said there was an urgent need for a simpler, quicker diagnostic test, officials from the World Health Organization said during a news briefing on Wednesday.

On trial runs in some states, the C.D.C. kits produced results that were “inconclusive,” Dr. Messonnier said. The tests did not involve samples from potential patients, but were part of the routine quality-control procedures that labs followed before using a test to make real diagnoses.

“Things may not always go as smoothly as we may like,” Dr. Messonnier said.

The problem appeared to come from one ingredient involved in the test, Dr. Messonnier said, adding that the C.D.C. would make a new supply of that ingredient to send to all of the laboratories. Officials did not say when the ingredient would be shipped, but said the process was being expedited and the material would be made available as soon as possible.

States that did not have trouble with the kits could keep using them, Kristen Nordlund, a spokeswoman for the C.D.C., said, adding that those states would still receive the newly made ingredient from the agency.

The flawed test kits are a separate issue from the mislabeled samples in San Diego that had led officials to discharge a woman, who was sick from the coronavirus, from a hospital.

More than 1,380 people have died, nearly all of them in China, where there are more than 55,000 confirmed cases.

The C.D.C. does not recommend testing for people who may have been exposed to the virus but have no symptoms. Even if they are infected, if they are still in the incubation period, there may not be enough virus in their bodies for the test to detect.

The inability to detect very early infections is one reason for keeping planeloads of people from Wuhan in quarantine instead of just testing them and letting them go if the results are negative. A person could test negative and still be infected.

For the same reason, health authorities say there is no benefit to testing symptom-free people on cruise ships.

Because there is an unknown window of time between when a person becomes infected and when the test can find the virus, health officials have determined that a quarantine of two weeks — believed to be the incubation period of the illness — is the best way to make sure that people who may be infected do not transmit the virus to others.

Tests for other infectious diseases can also fail to detect some cases. A panel of tests used to screen for respiratory viruses when pneumonia is suspected can give negative results even if a patient is infected, Dr. Marrazzo said. So can rapid tests for flu and strep throat. Blood tests for H.I.V. can miss the diagnosis in people who were recently infected.

“There is no perfect test for pretty much any infectious disease I can think of,” Dr. Marrazzo said.

Miriam Jordan contributed reporting.

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