A series of missteps at the nation's top public health agency caused a critical shortage of reliable laboratory tests for the coronavirus, hobbling the federal response as the pandemic spread across the country like wildfire, an Associated Press review found.

President Donald Trump assured Americans early this month that the COVID-19 test developed by the Centers for Disease Control and Prevention is "perfect" and that "anyone who wants a test can get a test." But more than two months after the first U.S. case of the new disease was confirmed, many people still cannot get tested.

In the critical month of February, as the virus began taking root in the U.S. population, CDC data shows government labs processed 352 COVID-19 tests — an average of only a dozen per day.

"You cannot fight a fire blindfolded," Tedros Adhanom Ghebreyesus, head of the World Health Organization, said at a recent briefing. "We cannot stop this pandemic if we don't know who is infected."

The Department of Health and Human Services, which includes the CDC, has begun an internal review to assess its own mistakes. But outside observers and federal health officials have pointed to four primary issues that together hampered the national response — the early decision not to use the test adopted by the World Health Organization, flaws with the more complex test developed by the CDC, government guidelines restricting who could be tested and delays in engaging the private sector to ramp up testing capacity.

Combined with messaging from the White House minimizing the disease, that fueled a lackluster response that missed chances to slow the spread of the virus, they said.

"There were many, many opportunities not to end up where we are," Dr. Ashish K. Jha, the director of the Global Health Institute at Harvard, told the AP. "Basically, they took this as business as usual. ... And that's because the messaging from the White House was 'this is not a big deal, this is no worse than the flu.' So that message basically created no sense of urgency within the FDA or the CDC to fix it."

Even as private labs have been cleared by government regulators to process tens of thousands of additional tests in the last two weeks, experts warn that the nation is still falling well short of enough testing capacity to keep ahead of the highly contagious virus. And it can often take a week just to get results back.

Trump last week rated his administration's response to the crisis as a perfect 10. However, Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases, said the CDC's system wasn't designed to test for and track a widespread outbreak, which he characterized as "a failing."

In interviews with the AP, two federal health officials with direct knowledge of the situation said CDC experts don't know why many of the agency's test kits failed to reliably detect the virus. The officials spoke on the condition of anonymity because they were not authorized to speak publicly about what went wrong.

J. Stephen Morrison, a health policy expert at the Center for Strategic and International Studies in Washington, called the testing issues a "debacle," contributing to what he described as a confused and delayed federal response to the crisis.

As a result, he said, the CDC has now been marginalized within the White House — a worrisome development.

"CDC has generally been regarded as the best in the game," Morrison said. "I don't think they

anticipated the technical difficulty or the speed with which the virus has been moving. The virus was racing out ahead of them."

FATEFUL DECISIONS

On New Year's Eve, Chinese scientists informed the World Health Organization about a cluster of 27 pneumonia cases of unknown cause in the industrial megalopolis of Wuhan that they linked to the city's wholesale fish market. Less than two weeks later, the Chinese had sequenced the virus' genetic makeup and shared it with the world.

Within days, German scientists had developed a test that could identify a unique part of the virus' DNA. The WHO quickly adopted the German test, publishing technical guidelines on Jan. 17 and working with private companies to produce testing kits.

As they have done with some past outbreaks, officials at the CDC headquarters in Atlanta decided to develop their own test, focusing on three gene targets distinct from what the WHO used. Over the decades, the headquarters lab had built a track record of being among the first to develop tests for new diseases and quickly making them available for disease tracking.

The CDC published the technical details for its COVID-19 test on Jan. 28, 10 days after the WHO. By then, the virus had already been in the U.S. for at least two weeks.

The 35-year-old man who would become the first American to test positive had arrived in Seattle on Jan. 15, following a trip to Wuhan. After swabs from his nose and throat were flown to the CDC lab, federal officials announced the results Jan. 21.

In an interview on CNBC the following day, the Republican president was asked about the risk to the nation.

"We have it totally under control," he said. "It's one person coming in from China. ... It's going to be just fine."

With limited capacity at the CDC lab in Atlanta, the agency placed strict criteria on who could be tested: people with fevers, coughing or difficulty breathing who had also visited Wuhan within the preceding two weeks or who had close contact with someone already confirmed or under investigation for having the virus.

On Jan. 30, the day the WHO declared the outbreak a public health emergency, Trump again assured the American people that the virus was "very well under control."

Then he departed for a weekend at his Mar-a-Lago club in Florida, where he tweeted a photo of himself playing golf at his club in West Palm Beach.

"Getting a little exercise this morning!" the president wrote.

The following day, the U.S. declared its own emergency. Still, U.S. citizens returning from China who did not have a fever weren't tested for the virus but were encouraged to self-quarantine at home for 14 days.

At that point, the CDC had confirmed just eight cases of COVID-19 in the U.S. The agency amended its testing criteria to include people with fevers who had traveled to China, rather than just Wuhan.

FLAWED TEST KITS

Four days after the U.S. declared a state of emergency, only 178 patients had been tested and 82 others were listed as "pending," meaning they were awaiting final results, according to CDC data released at the time.

To help increase the number of people being screened, the Food and Drug Administration issued emergency authorization for CDC-certified labs run by state health departments to begin processing swabs, and they were provided with kits that could test 250 patients.

As the first tests were processed at the state labs, technicians reported getting inconclusive

results, which the CDC has said could be due to the test looking for signs of generic coronaviruses, of which there are many, rather than the specific virus that causes COVID-19. Whatever the reason, by mid-February, only about a half-dozen state and local public health labs had reliable tests. But still, CDC Director Dr. Robert Redfield continued to insist his agency had developed "a very accurate test."

"We found that, in some of the states, it didn't work," Redfield said earlier this month. "We figured out why. I don't consider that a fault. I consider that doing quality control. I consider that success."

The testing problems emerged just as the CDC broadened its criteria to include patients who were "severely ill" with COVID-19 symptoms "even if a known source of exposure has not been identified."

As more sick people sought to be tested, many states were forced to limit access because of the flawed CDC test. Accounts began to emerge through social media of people with all the symptoms of COVID-19 who either couldn't get tested or had test results delayed by days or even a week.

"I know of doctor friends of mine who have critically ill patients in the ICU, and we don't know if they have COVID or not because we can't get a test," Jha said last week.

COMMUNITY TRANSMISSION

On Feb. 24, exasperated officials at the Association of Public Health Laboratories sent a letter to the FDA, basically asking permission for state labs to develop their own tests. Within days, the FDA reversed its previous position and said both public and private labs could conduct testing.

Trump continued to insist the virus would die out on its own. "One day, it's like a miracle. It will disappear," he predicted Feb. 27.

By then, experts say, the opportunity to halt the relentless spread of the virus within the U.S. population had been lost.

On Feb. 29, only 472 patients had been tested nationwide, with just 22 cases confirmed, according to CDC data. Of those, nine cases were not related to travel but had spread person-to-person within the U.S.

By comparison, South Korea had its first confirmed case of COVID-19 on Jan. 20, the same day as the U.S. Officials there used a test that focused on the same gene targets as the WHO test, according to the website of a test manufacturer. They then quickly permitted private-sector labs to run the samples. As a result, a nation with less than one-sixth the population of the U.S. mobilized to test more than 20,000 people a day.

South Korea also instituted drive-thru centers, allowing quicker identification of those who were infected but might not be displaying symptoms, thus slowing the emergence of new cases to a more manageable level.

Meanwhile, the rate of U.S. infections soared.

"The system is not really geared to what we need right now, what you are asking for," Fauci conceded during a congressional hearing earlier this month. "That is a failing. Let's admit it."

SHIFTING BLAME

As public outrage over the lack of available U.S. tests grew, the FDA announced it would allow private diagnostic lab companies to produce new tests without preauthorization from regulators. Trump and HHS Secretary Alex Azar visited the CDC lab in Atlanta on March 6, praising the agency's performance and promising 4 million test kits would be available by the end of the following week.

That lofty number didn't match the ability of U.S. labs to process tests, however. Private providers were just then ramping up, while CDC and state health labs processed about 25,200 COVID-19 tests in the following seven days, according to CDC data.

At the same news conference, Trump said he wanted infected passengers to remain on a cruise ship off the West Coast to keep the number of confirmed COVID-19 cases in the U.S. low.

"I like the numbers being where they are," Trump said, shortly before departing Atlanta for another weekend of golf in Florida. "I don't need to have the numbers double because of one ship that wasn't our fault."

Trump has also attempted to mislay blame for the testing troubles on the Obama administration. In 2018, Trump disbanded the White House directorate charged with preparing for and responding to global pandemics.

"I don't take responsibility at all," Trump replied when asked about the testing shortfall in a March 13 briefing at the White House.

Morrison said Trump appears to see the virus as a political issue rather than a public health threat.

"You can imagine a White House that said, 'Do whatever it takes to test everybody for the virus,'" he said. "That wasn't the mentality. It was the opposite mentality, and ultimately the responsibility to protect the American people lies with the White House."

Trump and other officials have falsely said they declined to use the WHO test because it isn't reliable.

"Quality testing for our American people is paramount to us," Deborah Birx, who is coordinating the U.S. coronavirus response, said last week. "It doesn't help to put out a test where 50% or 47% are false positives."

"It was a bad test," Trump chimed in.

Tarik Jašarević, a WHO spokesman, told the AP last week that his agency had shipped 1.5 million testing kits manufactured in Germany to 120 countries around the globe, with no such problems emerging.

"The test has been validated in three external laboratories, adapted by WHO and manufactured in line with international quality standards," he said. "It has shown consistently good performance in laboratory and clinical use, and neither a significant number of false-positive nor false-negative results have been reported."

Over the past two weeks, U.S. testing capacity has surged, with private companies joining in. LabCorp began providing tests March 5, and Quest Diagnostics followed four days later. Tests also are being conducted at hospitals and other centers.

With the increased testing has come a skyrocketing number of confirmed cases, zooming from 43 at the beginning of March to 33,404 by Monday.

Only in the last few days has the United States finally begun testing more people each day than far smaller South Korea, according to data complied by Johns Hopkins University.

Jha estimates the U.S. should be testing 100,000 to 150,000 people per day — figures he said should be obtainable given the number of high-quality diagnostic labs in the country.

"We certainly have the capacity. It's just we're not doing it," Jha said Thursday. "We are up to about 40,000 tests per day now — and so we are moving in the right direction. Still far from where we need to be, but moving."--Net