

Accuracy still unknown for coronavirus tests

By **MATTHEW PERRONE**
Associated Press

WASHINGTON — How accurate are the coronavirus tests used in the U.S.?

Months into the outbreak, no one really knows how well many of the screening tests work, and experts at top medical centers say it is time to do the studies to find out.

When the new virus began spreading, the Food and Drug Administration used its emergency powers to OK scores of quickly devised tests, based mainly on a small number of lab studies showing they could successfully detect the virus.

That’s very different from the large patient studies that can take weeks or months, which experts say are needed to provide a true sense of testing accuracy.

The FDA’s speedy response came after it was initially criticized for delaying the launch of new tests during a crisis and after the Centers for Disease Control and Prevention stumbled in getting its own test out to states.

But with the U.S. outbreak nearly certain to stretch on for months or even years, some experts want the FDA to demand better evidence of the tests’ accuracy so doctors know how many infections might be missed.

There have been more than 2 million confirmed coronavirus cases in the U.S. and more than 115,000 deaths, according to data compiled by Johns Hopkins University. Cases in nearly half of U.S. states are rising.

The FDA on Monday revoked emergency authorization for malaria drugs promoted by President Donald Trump for treating COVID-19 amid growing evidence they don’t work and could cause serious side effects.

The FDA said the drugs hydroxychloroquine and chloroquine are unlikely to be effective in treating the coronavirus. Citing reports of heart complications, the FDA said the drugs’ unproven benefits “do not outweigh the known and potential risks.”

The decades-old drugs, also prescribed for lupus and rheumatoid arthritis, can cause heart rhythm problems, severely low blood pressure and muscle or nerve damage.

In recent weeks, preliminary findings have flagged potential problems with some COVID-19 tests, including one used daily at the White House. Faulty tests could leave many thousands of Americans with the incorrect assumption that they are virus-free, contributing to new flare-ups of the disease as communities reopen.

“In the beginning, the FDA was under a lot of pressure to get these tests onto the marketplace,” said Dr. Steven Woloshin of Dartmouth College, who wrote about the issue in the New England Journal of Medicine last week. “But now that there are plenty of tests out there, it’s time for them to raise the bar.”

The FDA said in a statement that it has already asked multiple test makers to do follow-up accuracy studies, although it didn’t say for how many of the more than 110 authorized screening tests. The agency also said it



A nurse uses a swab to perform a coronavirus test in Salt Lake City.

Rick Bowmer/AP Photo

FOR NOW, MOST COVID-19 TESTS IN THE U.S. DON’T GIVE DATA ON REAL-WORLD PERFORMANCE, INCLUDING HOW OFTEN THE TESTS FALSELY CLEAR PATIENTS OF INFECTION OR FALSELY DETECT THE VIRUS.

is tracking reports of problems. Accuracy has also been an issue with blood tests that look for signs of past infections.

No screening test is 100% accurate. So details on accuracy are routinely provided for tests of all types, including seasonal flu, hepatitis, HIV and cancers. For example, rapid flu tests are known to miss 20% or more of all cases, a factor doctors weigh when treating patients who have symptoms but test negative.

For now, most COVID-19 tests in the U.S. don’t give data on real-world performance, including how often the tests falsely clear patients of infection or falsely detect the virus. That information is lacking for all but a few of the roughly 80 commercial screening tests available, according to an Associated Press review.

The government’s emergency authorization process “requires a lower level of evidence,” the agency said. Makers need only show that a test “may be effective” instead of the usual requirement to demonstrate “safety

and effectiveness.” They would have to meet that higher threshold once the U.S. government declares the emergency over.

Many of the commercial test makers submitted results from 60 samples, the minimum number required and mostly used lab-produced specimens of the virus. The FDA now recommends the use of nasal swabs or other real samples from people screened for coronavirus.

Experts say larger patient studies are needed to assess a test’s true performance.

Lab testing bears little resemblance to actual — sometimes imperfect — conditions at hospitals, clinics and testing sites noted Dr. Robert Kaplan of Stanford University.

“You’re testing people in parking lots, the patients themselves are extremely anxious and often unable to follow instructions,” said Kaplan, a former associate director of the National Institutes of Health.

Kaplan and others say those differences could explain why some tests are not performing as expected.

Last month, the FDA warned doctors of a potential accuracy problem with Abbott Laboratories’ rapid ID Now test, which delivers results in roughly 15 minutes. The test has been lauded by Trump and used to screen the president, his staff and visitors to the White House.

The FDA alert followed a preliminary report by New York University that found Abbott’s test missed between a third to one-half of infections caught by a rival test in patients screened for the virus.

Abbott rejected the findings, saying the researchers did not follow the instructions for using its test. The company pointed to alternate patient studies, including its own, that have found the test successfully detects between 91% and 95% or more of virus cases when compared to other tests.

Cover your sneeze

Dear Annie: Throughout the coronavirus pandemic, my husband doesn’t cough or sneeze into his arm. He sometimes coughs into his hand. No matter how hard I try to instill in him how he could be affecting everyone in the household, he argues that it’s bull.

His excuses include that he doesn’t want to get his shirt sleeve or bare arm messed up, or that he forgets. Is there any way you can put in print how important this is? Thank you. — *Mind Your Manners*

Dear Mind Your Manners: Your husband might say that your requests are baloney, but it sounds like he is being the bully here. Sneezing into his hand is disgusting and affects everyone around him. Continue to tell him to knock it off, and if need be, schedule a call with your medical doctor, who can go over the importance of using a tissue or sneezing into your elbow. Tell your husband that if he has to sneeze, he should excuse himself and get as far away from everyone as possible. You might also want to invest in a good, old-fashioned handkerchief.

DEAR ANNIE



ANNIE LANE
Creators
Syndicate Inc.

Dear Annie: This is regarding the woman who had a problem with her sister’s husband, who refused to come into the house to a gathering because he would have to take off his shoes. You are probably right that he is a stubborn louse.

But here is another thought that people who have historic wood floors in a house surrounded by gravel should consider. They can acquire shoe coverings in several sizes, like the ones house tours sometimes require, and offer them to visitors if they are uncomfortable in their stocking feet for whatever reason.

My sister has those. She bought them because I have had major reconstructive foot surgery on both feet, which means that I have no natural padding in my heels. I only wear tie shoes with supportive inserts to support and cushion my feet. If I were to have to go just with socks on a hardwood floor, I would gingerly hobble to the nearest chair and sit there the whole party.

To avoid ever having to do this, I keep a few of the coverings from my sister in the car so I can go back and get them if need be. However, I have never had to get them, because my other friends are tolerant of my shoes, even though they and other guests are in stocking feet.

People who have never had such foot problems may not realize the torture that going in stocking feet could be causing someone else. — *A Sister With Extreme Foot Problems*

Dear Foot Problems: Disposable booties are a great suggestion. Thank you!

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Saturday’s Cryptoquip: WHAT COULD IT BE CALLED WHEN RESIDENTS OF PARIS OR MARSEILLES BECOME CLOSE CHUMS? FRENCH-SHIP.

Today’s Cryptoquip Clue: B equals C

6-16CRYPTOQUIP

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HKMRVWN BKJDU NWLBS XMVK

HT DKJFWNWU IXMUKI BKFWN?

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