

Rapid, cheap, home tests for coronavirus are in the works, but accuracy is an issue

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Ohio Gov. Mike DeWine tweeted early Thursday that he had tested positive for the coronavirus and would not be greeting President Donald Trump. Hours later, DeWine announced that two different tests had

come back negative.

There, in a nutshell, is the nation's next pandemic testing dilemma.

DeWine first had an 'antigen' [test](#)—fast and convenient, but not very reliable. Then he had two high-accuracy, lab-based molecular tests—the kind that have been a technical, logistical, and public health nightmare in the United States. Most molecular test results now are so delayed that they are practically useless in curbing the spread of the virus.

Is it possible to find a risk-benefit balance between accuracy and convenience? Some governors, including DeWine, and prominent scientists believe the answer is yes.

"Simple at-home tests for the [coronavirus](#), some that involve spitting into a small tube of solution, could be the key to expanding testing and impeding the spread of the pandemic," Harvard Medical School epidemiologist and testing expert Michael Mina wrote in a New York Times op-ed. "The Food and Drug Administration should encourage their development and then fast track approval."

When a virus invades the body, it starts producing a signature protein—an antigen—to which the immune system responds by making disease-fighting antibodies. Antigen tests work well when lots of antigen is present. But in the early days of an infection, when the viral load is low, an antigen test may be no better than a coin flip.

Molecular tests, in contrast, can detect minute quantities of fragments of viral genetic material in a nasal swab. Yet even this technology misses as many as 30% of infections, studies suggest.

So far, the U.S. Food and Drug Administration has approved two coronavirus antigen tests, one made by Becton Dickinson (BD), the other

by Quidel. While the tests can provide results in as little as 15 minutes using a nasal specimen, they are not home tests. These are "point-of-care" tests that have to be done in a clinic, nursing home, or doctor's office that has installed the companies' testing platforms.

Even so, a bipartisan group of seven governors, including DeWine, is banking on point-of-care antigen testing to expand and speed diagnosis. This week, the governors partnered with the Rockefeller Foundation to pursue a deal for 3.5 million antigen tests. Discussions are underway with BD and Quidel.

Meanwhile, the Centers for Medicare and Medicaid Services plans to send antigen tests to nursing homes throughout the country, according to Pennsylvania Secretary of Health Rachel Levine.

"That's going to be a challenge, and what we're concerned about is the sensitivity and the specificity of those tests, meaning the false negative rate and the false positive rate," Levine said this week.

Mina, at Harvard, envisions the next innovation: cheap, at-home antigen assays that are as easy to use as a pregnancy test. That would enable people with no COVID-19 symptoms—or no symptoms yet—to know they are infectious and need to self-isolate for 10 days.

"One variety, paper-strip tests, are inexpensive and easy enough to make that Americans could test themselves every day," Mina wrote in the Times. "You would simply spit into a tube of saline solution and insert a small piece of paper embedded with a strip of protein. If you are infected with enough of the virus, the strip will change color within 15 minutes."

He believes the speed and frequency of such testing would offset the chance of error. Even if an at-home antigen test is 1,000 times more

likely to miss an early infection than a molecular test, the virus is reproducing so rapidly that the [antigen test](#) would probably turn positive if repeated within 24 hours.

Other experts see antigen testing as promising, but not a panacea. False alarms could be almost as bad as missed infections. DeWine, for example, was going to self-quarantine until he discovered it wasn't necessary.

A number of companies and academic labs are racing to develop at-home tests. These include E25Bio, Sherlock Biosciences, Mammoth Biosciences, and OraSure, based in Bethlehem, Pa.

Whether the lower reliability of home tests will be an obstacle to FDA approval remains to be seen. The FDA has relaxed its requirements because of the public health emergency. But in guidance issued last week, the agency said non-prescription, at-[home tests](#) should be only 10% less accurate than [molecular tests](#) at detecting an infection, and 1% less accurate at ruling it out.

"As of now, I really haven't seen FDA stand in the way," E25Bio executive Carlos-Henri Ferre told 360DX, a diagnostics industry news website.

But he also said regulators will have to wade into uncharted territory, including whether positive home test results should be reported to public health authorities, and safe disposal of potentially infectious test specimens.

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