University Of Colorado Boulder Saliva-Based COVID Test

University of Colorado-Boulder

Researchers at the University of Colorado Boulder have developed a rapid COVID-19 saliva test that renders results in 45 minutes. They've now spun off a company, Darwin Biosciences, to commercialize the test.

> *"We are facing a serious testing shortage in this country right now as more people want to get tested and diagnostics labs are overwhelmed," said Nicholas Meyerson, a postdoctoral associate in the Sawyer Lab at the BioFrontiers Institute at CU Boulder. "We've developed a test that could get results to people much faster."*

The test is reverse-transcription loop-mediated isothermal amplification (RT-LAMP). It is designed for widespread screening of asymptomatic individuals, who may make up as many as 70 percent of cases. A user spits in a tube, adds a stabilizing solution, closes the lid and hands it to testing staff, who can complete the test at the same location (point-of-need testing.) It is processed through a simple system of pipettes, heating sources and an enzyme mixture. The sample is heated to inactivate potential pathogens and liberate any viral genome from the test liquid, then added to

two tubes containing a custom enzyme mixture which when heated undergoes a chemical reaction where SARS-CoV-2 genetic material is detectible. Results are colorimetric: should the sample remain pink, it's negative; if it turns yellow, the test is positive.

Since no swabs, elaborate equipment, or specially trained personnel are required, the tests are less vulnerable to backlogs and supply chain shortages. In addition, saliva procurement is completed by the user, avoiding the need for multiple nurses or technicians, reducing costs and speeding the process.
In one experiment, researchers conducted a "contrived clinical validation," spiking half the saliva samples with inactivated SARS-CoV-2 in the lab. The samples were shuffled and given to another scientist to test with the RT-LAMP technology.

"The test predicted with 100% accuracy all of the negative samples, and 29 of 30 positive samples were predicted accurately," said Meyerson, noting that the 30th test was scored as inconclusive. Additional second-party validation tests are underway.

The researchers note that the test is slightly less sensitive than those performed in clinical labs. But a separate computer modeling study completed at the BioFrontiers Institute found that quick turnaround is more critical to curbing the pandemic than test sensitivity.

"Our modeling showed that whether a test is sensitive or super-sensitive is not that important," said BioFrontiers Director Roy Parker, co-author of that paper, which has not yet been peer reviewed. "What is important is frequent testing, with the test results returned as fast as possible, which identifies more infected people faster and can limit new infections."

Ideally, the team sees the test as a "surveillance tool."

"While we are all very optimistic about a coronavirus vaccine, scientists have been working on an HIV vaccine for 30 years without success," said Professor Sara Sawyer, a virologist in the Department of Molecular Cellular and Developmental Biology who led the development of the test. "Meantime, the HIV pandemic showed us that pervasive testing can make a big difference."

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