Researchers develop more reliable rapid tests for COVID-19

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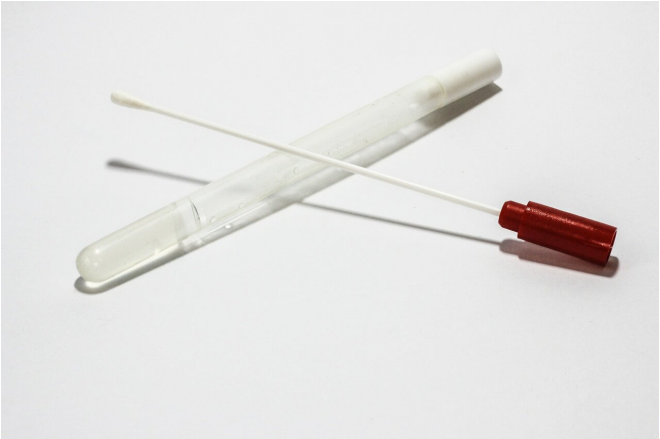

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Researchers at the University of Maryland School of Medicine (UMSOM) have developed two rapid diagnostic tests for COVID-19 that are nearly as accurate as the gold-standard test currently used in laboratories. Unlike the gold standard test, which extracts RNA and uses it to amplify the DNA of the virus, these new tests can detect the presence of the virus in as little as five minutes using different methods.

One test is a COVID-19 molecular diagnostic test, called Antisense, that uses electrochemical sensing to detect the presence of the virus. The other uses a simple assay of gold nanoparticles to detect a color change when the virus is present. Both tests were developed by Dipanjan Pan, Ph.D., Professor of Diagnostic Radiology and Nuclear Medicine and Pediatrics at UMSOM and his research team. Dr. Pan has a joint appointment at the University of Maryland Baltimore County (UMBC).

"These tests detect the presence of the virus within 5 to 10 minutes and rely on simple processes that can be performed with little lab training," said Dr. Pan. They do not require the extraction of the virus's RNA—which is both complicated and time consuming.

They also are more reliable than the rapid antigen tests currently on the market, which detect the virus only in those with significantly high viral levels. "These two newer tests are extremely sensitive and can detect the presence of the virus, even in those with low levels of the virus," Dr. Pan said.

Dr. Pan's team included UMSOM research fellow Maha Alafeef, UMSOM research associate Parikshit Moitra, Ph.D., and research fellow Ketan Dighe, from UMBC.

Last month, the U.S. Food and Drug Administration (FDA) registered the laboratory of Dr. Pan as an approved laboratory development site for the Antisense test. The move paves the way for Dr. Pan's laboratory to begin conducting the test at the university, in research settings, as it undergoes further development.

In February, RNA Disease Diagnostics, Inc. (RNADD) received an exclusive global license from UMB and UMBC to commercialize the test. Dr. Pan serves as an unpaid scientific advisor to the company.

This test detects the virus in a swab sample using an innovative technology called electrochemical sensing. It uses a unique dual-pronged molecular detection approach that integrates electrochemical sensing to rapidly detect the SARS-CoV-2 virus.

"The final prototype is like a glucometer, which patients with diabetes use at home to measure their blood glucose levels," said Dr. Pan, "and is just as easy for people to do themselves."

Dr. Pan and his colleagues, in collaboration with RNA Disease Diagnostics, are launching a study of NBA basketball players in New York City to

compare the Antisense test to rapid COVID tests that the NBA is using to monitor COVID infections in its players.

"We would like to see whether our test can yield more reliable results compared to the existing platforms," he said. "Current antigen-based rapid COVID tests miss infections about 20 percent of the time and also have high rates of false positive results. Our Antisense test appears to be about 98 percent reliable, which is similar to the PCR test."

Similar to the Antisense test, the second rapid test also does not require the use of any advanced laboratory techniques, such as those commonly used to extract RNA, for analysis. It uses a simple assay containing plasmonic gold nanoparticles to detect a color change when the virus is present. In April, Dr. Pan and his colleagues published a stepwise protocol in the journal *Nature Protocols,* explaining how the nano-amplified colorimetric test works and how it can be used.

Once a nasal swab or saliva sample is obtained from a patient, the nucleic acid (bits of genetic material) in the sample is amplified via a simple process that takes about 10 minutes. The test uses a highly specific molecule attached to the gold nanoparticles to detect a particular protein. This protein is part of the genetic sequence that is unique to the novel coronavirus. When the biosensor binds to the virus's gene sequence, the gold nanoparticles respond by turning the liquid reagent from purple to blue.

"Innovations in COVID-19 testing remain incredibly important even as the epidemic appears to be waning in this country," said E. Albert Reece, MD, Ph.D., MBA, Executive Vice President for Medical Affairs, UM Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine. "As we continue to monitor infections in unvaccinated segments of our population and the potential spread of new variants, there will be a vital need for inexpensive rapid tests to ensure that we continue to maintain low infection rates."

More information: Maha Alafeef et al, RNA-extraction-free nano-amplified colorimetric test for point-of-care clinical diagnosis of COVID-19, *Nature Protocols* (2021). DOI: 10.1038/s41596-021-00546-w

Provided by University of Maryland School of Medicine

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