Lab-on-a-chip COVID-19 antibody test could offer rapid, accurate results

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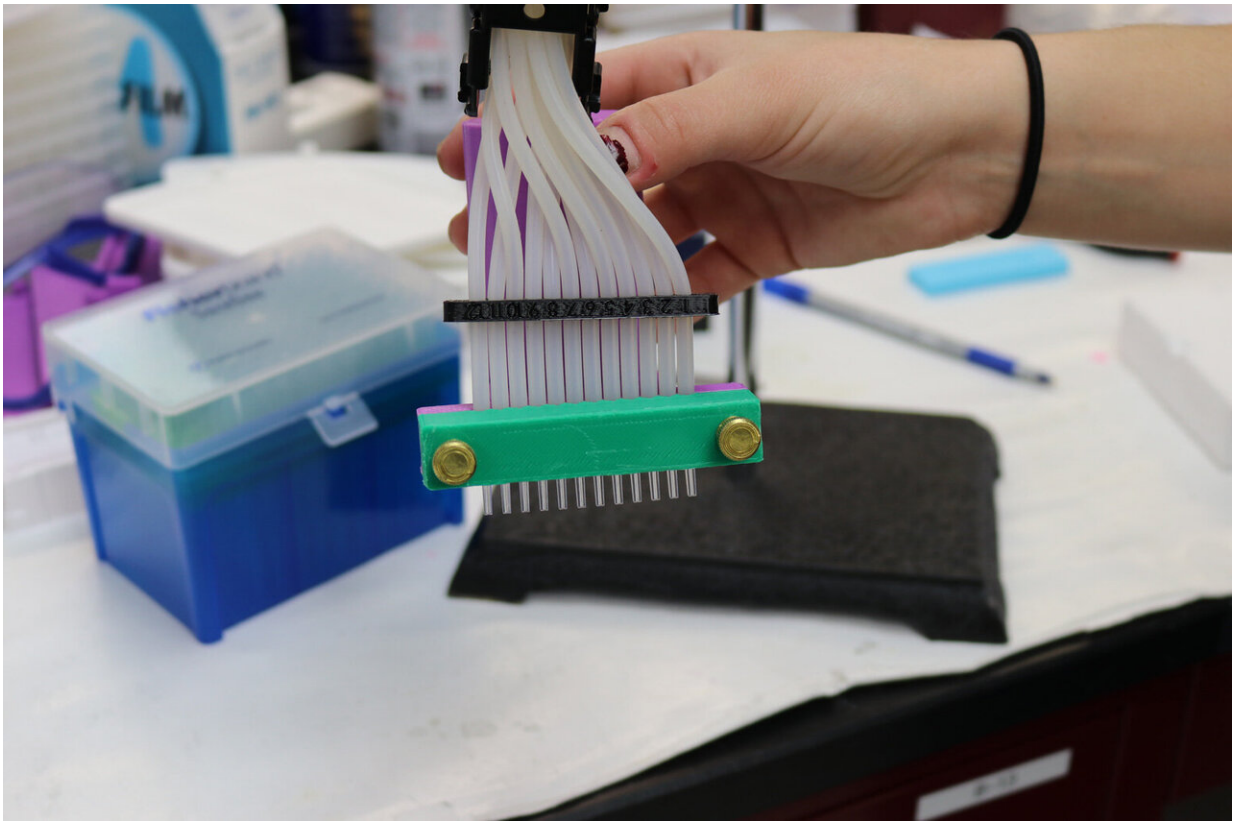

Credit: Optofluidic Bioassay, LLC

COVID-19 antibody testing that's portable, fast, cheap and highly precise—four attributes that are usually mutually exclusive—could be possible with a microfluidic device invented at the University of

Michigan and developed by U-M startup Optofluidic Bioassay.

A microfluidic device, or "lab on a chip," shrinks multiple lab functions onto a single chip just millimeters or centimeters in size. The technology enables faster results with smaller sample sizes.

The new system is believed to be the first microfluidic approach to a gold standard testing protocol known as "enzyme-linked immunosorbent assay," or ELISA. The U-M researchers have previously published results showing that their device can work as well as the slower, larger, standard ELISA set-up. They're currently validating it for use on COVID-19 antibodies.

They've demonstrated that they can detect synthetic COVID-19 antibodies and they're working with researchers at a hospital in New Jersey on experiments with human blood from COVID-19 patients.

University and industry labs around the U.S. are clambering to develop better antibody tests. The U-M approach is different in that it centers on a device, rather than the chemical mixtures, or reagents, to detect COVID-19 markers.

"We are unique because we are a hardware company," said Xudong (Sherman) Fan, U-M biomedical engineering professor and co-founder of Optofluidic Bioassay. "Anyone working on COVID-19 antibody tests can use their reagents in our device."

Why we need antibody tests

Rapid and accurate antibody tests could play an important role as governments, medical workers, scientists and private citizens alike continue to navigate the pandemic. Antibody tests can reveal who has already been exposed to the virus and developed immunity, at least

temporarily, and can safely go back to work. If done in a widespread way, they could show the true scale of the pandemic and its death rate.

And the U-M researchers say their particular approach could give doctors critical, near-real-time insights into how a patient is responding to treatment, or a vaccine once one is developed.

Small-scale antibody testing has been done in some countries. Research projects are underway in the U.S. and while kits are beginning to materialize on the market here, they're not yet widely available.

Antibody, or "serology" tests are different from the "PCR" tests being used to diagnose COVID-19. Rather than screen for the virus itself, serology tests detect antibodies—proteins the immune system manufactures to fight it.

Microfluidic ELISA in the landscape of COVID-19 antibody tests

The majority of labs working on serology kits are making a particular type called "rapid diagnostic tests" that give a yes or no reading. These are quick, but they have drawbacks. False positives can be a problem. And because they don't give a lot of information, they aren't useful in monitoring the immune system's response during treatment.

A handful of labs are making ELISA tests. These are typically quantitative and accurate, showing the concentration of antibodies. That makes them more reliable and less prone to false positives than the rapid diagnostic tests. But standard ELISA results take several hours, and the machines that provide them are the size of refrigerators. In addition, the sample needs to be sent to the test lab for analysis.

But microfluidic ELISA can give a quantitative and accurate result in

just 15 minutes, with a finger-prick's worth of blood. This combination of attributes, plus the fact that it's portable, could make it a powerful tool.

"Our approach offers the best of both worlds. We can achieve the quickness and simplicity of the rapid diagnostic test with the accuracy of the standard ELISA quantitative measure," Fan said.

"Because our device generates such sensitive and quantitative measurements, we believe its use goes beyond identifying recovered patients. Antibodies begin to show up a few days after infection, so we could use this approach to monitor patients' immune response to infection, treatment, and vaccination."

The microfluidic ELISA is rapid, portable, and low cost.

"The estimated cost of testing is a few dollars per test of two to three different antibodies, making this a very viable option for use in hospitals, doctors' offices, field clinics, and potentially even pharmacies," said Xiaotian Tan, a doctoral student in biomedical engineering who is working on COVID-19 antibody testing with Fan.

The machine can be the size of a microwave, and can test up multiple simultaneous samples of little more than a drop of blood from a fingertip in less than 20 minutes.

It was invented at U-M several years ago and developed by Optofluidic Bioassay, which was founded by Fan and former research investigator of biomedical engineering, Maung (Malcolm) Khaing Oo, who now serves as the company's chief technology officer. Xudong Fan and Maung Khaing Oo are co-founders of and have an equity interest in Optofluidic Bioassay, LLC. The researchers plan to eventually apply for FDA Emergency Use Authorization.

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