New testing platform for COVID-19 is an efficient and accurate alternative to gold-standard RT-qPCR tests

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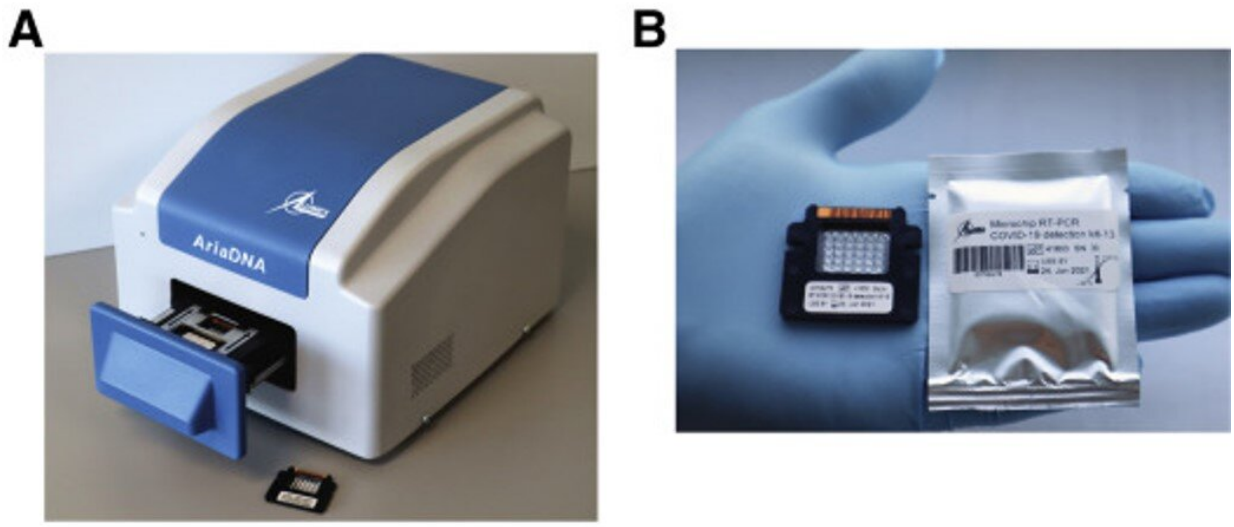

A) AriaDNA analyzer. B) Microchip for coronavirus disease 2019 detection with lyophilized reagents in the microwells displayed along with its packaging. Credit: Lumex Instruments Canada

Throughout the COVID-19 pandemic, supply chain shortages of reagents and test kits have limited the rapid expansion of clinical testing needed to contain the virus. Investigators have developed and validated a new microchip real-time technology platform that uses 10-fold less

reagents compared to Centers for Disease Control and Prevention (CDC)-approved tube-based RT-PCR tests, and reports results in as little as 30 minutes. Its accuracy was 100 percent predictive in clinical samples, investigators explain in the *Journal of Molecular Diagnostics*.

"Sensitivity is critical for early detection of COVID-19 infection where the viral load is minimal to prevent further spreading of the disease. During this pandemic, numerous testing assays have been developed, sacrificing sensitivity for speed and cost," explains lead investigator Peter J. Unrau, Ph.D., Department of Molecular Biology and Biochemistry, Simon Fraser University, Burnaby, BC, Canada. "This research offers a cheaper, faster alternative to the most reliable and sensitive test currently used worldwide, without sacrificing sensitivity and reproducibility."

Researchers validated a microchip PCR technology for detection of SARS-CoV-2 in clinical samples. Empty microchips with 30 microwells were manufactured from aluminum sheets and coated with surface modifiers. They were then filled with CDC-authorized primers and probes to detect SARS-CoV-2. They were individually packaged and sent to a laboratory for sample validation and testing. Real-time qPCR was performed using 1.2 microliter reaction volume per reaction on a microchip-based PCR analyzer using AriaDNA software to control the instrument and obtain PCR results.

Nasopharyngeal swabs from eight patients with positive COVID-19 test results and 13 patients with negative COVID-19 test results were collected at St. Paul's Hospital in Vancouver, Canada and tested with the microchip RT-qPCR kit. Of the 21 patient samples, eight tested positive, 12 tested negative, and one included sample was invalid, which tested negative in both the microchip RT-qPCR assay and hospital testing. The CDC standards deemed the sample invalid as the human internal control was not detected in this sample. The microchip kit miniaturized the

reaction volumes needed by 10-fold, resulting in lower reagent consumption and faster assay times (in as little as 30 minutes compared to about 70 minutes), while maintaining the same gold standard in sensitivity as higher volume techniques. Because the kit comes preloaded with SARS-CoV-2 primers and probes, it may further reduce operator-associated errors, improving the reliability of analysis in remote settings.

Available internationally, the low-energy (100 watt), compact, lightweight microchip analyzer and COVID-19 detection kits developed by Lumex Instruments Canada and validated by Dr. Unrau and his colleagues may enable point-of-care testing in remote locations, clinics, and airports.

"Although further testing of additional clinical samples and sample types may be needed before this assay can be widely deployed," Dr. Unrau says, "these preliminary results demonstrate a promising, versatile technology that can be easily configured and mobilized to detect infections of current and future emerging viruses, overcoming current bottlenecks and ensuring a faster response in the future."

More information: Razvan Cojocaru et al, Microchip RT-PCR Detection of Nasopharyngeal SARS-CoV-2 Samples, *The Journal of Molecular Diagnostics* (2021). DOI: 10.1016/j.jmoldx.2021.02.009

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