Researchers validate clinical feasibility for CRISPR-based COVID-19 testing at point of care

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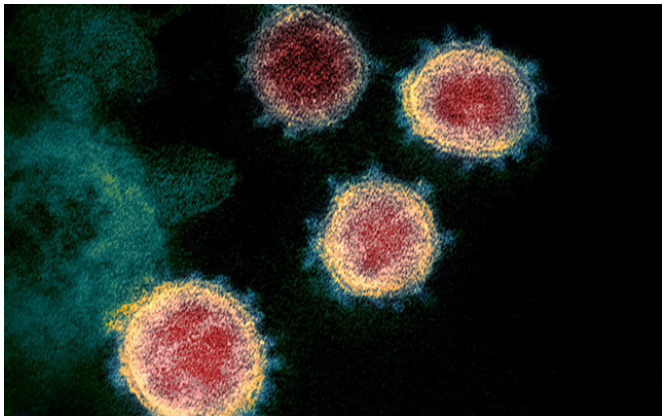

A colorized scanning electron micrograph of the SARS-CoV-2 virus. Credit: NIAID

In March, researchers in the Department of Biomedical Engineering—a shared department in the schools of Dental Medicine, Medicine, and Engineering—began to develop a new, low-cost, CRISPR-based diagnostic platform to detect infectious diseases, including HIV virus, the novel coronavirus (SARS-CoV-2). Today, the method is one step closer to being a cutting-edge diagnostics technology for rapid detection of infectious diseases.

Lead by associate professor Changchun Liu, the "All-In-One-Dual CRISPR-Cas12a" (AIOD-CRISPR) method enables simple, rapid, ultrasensitive, visual detection of SARS-CoV-2, intended for use at home or in small clinics.

In a paper published in *Nature Communications*, the researchers validated the clinical feasibility of the platform using COVID-19 clinical swab samples. Additionally, the researchers used a low-cost hand warmer as an incubator to detect clinical sample results within 20 minutes.

"The usage of disposable hand warmers to heat the AIOD-CRISPR assay eliminates need for expensive electric equipment, enabling instrument-free point of care molecular diagnostics of COVID-19," says Liu.

The publication was co-authored by postdoctoral researchers Xiong Ding and Kun Yin; Ph.D. student Ziyue Li; professor and Associate Dean for Research Dr. Rajesh Lalla; Dr. Enrique Ballesteros, associate professor and chair, pathology and laboratory medicine; and Dr. Maroun Sfeir, assistant professor in pathology and laboratory medicine.

Nucleic acid amplification testing (PCR/RT-PCR) is currently the most sensitive and specific method for early detection of pathogens, but is not suitable for rapid point-of-care diagnostics because of the need for specialized laboratory equipment and trained technicians. Highly contagious pathogens, however, need real-time monitoring to prevent spreading from person to person.

In the study, Liu and his team evaluated their AIOD-CRISPR method using the RNA extract of 28 clinical COVID-19 swab samples, which included eight COVID-19 positive samples. To ensure the reliability of detection, each sample was tested twice in two independent trials. All eight of the COVID-19 positive samples were identified as positive in 40 minutes, which was also confirmed by visual detection. The results were also consistent with those of the CDC-approved RT-PCR method.

The researchers also used a low-cost hand warmer as an incubator to detect the patient samples to eliminate the need for an electric incubator. The AIOD-CRISPR tubes were directly placed on an air-

activated hand warmer, and the results were visible by the naked eye under LED light. Two COVID-19 positive samples incubated in the hand warmer bag were visually detected and identified as positive in 20 minutes.

"Such simple, portable and sensitive detection platform has the potential to provide rapid and early diagnostics of COVID-19 and other infectious diseases at home, in doctor's office, and even at drive-thru testing sites," says Liu.

More information: Xiong Ding et al. Ultrasensitive and visual detection of SARS-CoV-2 using all-in-one dual CRISPR-Cas12a assay, *Nature Communications* (2020). DOI: 10.1038/s41467-020-18575-6

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