FDA approves first at-home saliva collection test for coronavirus

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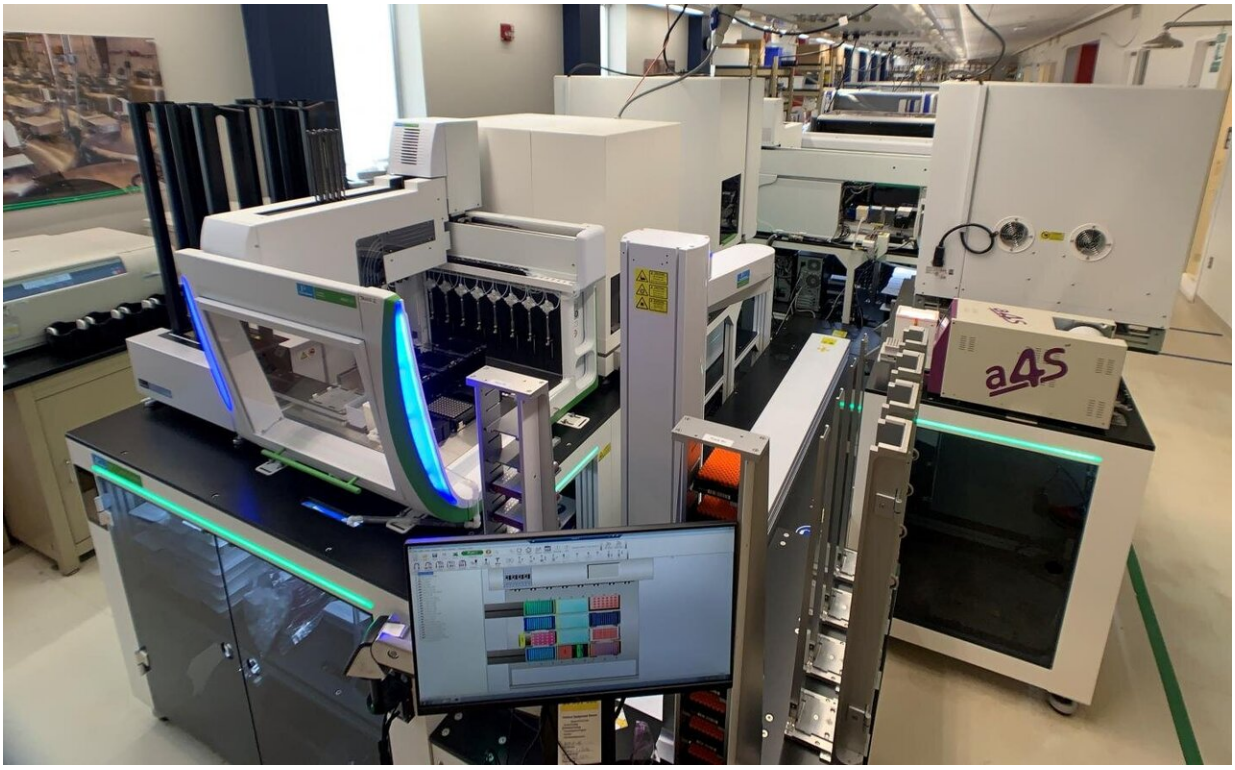

This fully automated nucleic acid extraction workstation at Rutgers' RUCDR Infinite Biologics can process up to 10,000 saliva samples per day for SARS-CoV-2 coronavirus testing. Credit: David Sokolowski

Rutgers' RUCDR Infinite Biologics received an amended emergency use authorization from the FDA late Thursday for the first SARS-CoV-2 coronavirus test that will allow people to collect their own saliva at home

and send to a lab for results.

The decision follows the FDA's recent emergency approval to RUCDR Infinite Biologics for the first saliva-based test, which involves health care workers collecting saliva from individuals at testing sites.

The new at-home saliva self-collection assay, developed by RUCDR in partnership with Spectrum Solutions and Accurate Diagnostic Labs, allows for broader screening than through the standard method using nose and throat swabs at a healthcare facility or testing location that requires a physical interaction with a healthcare professional.

"The impact of this approval means that not only do we no longer have to put healthcare professionals at risk for infection by performing nasopharyngeal or oropharyngeal collections, we can now preserve precious PPE for use in patient care instead of testing and can significantly increase the number of people collected each and every day in places other than a healthcare setting," said Andrew Brooks, chief operating officer and director of technology development at RUCDR, who also is a professor in the School of Arts and Sciences Department of Genetics at Rutgers University-New Brunswick.

"This will enable testing for people that do not have the means to get to a collection center and/or are at home because they are sick, quarantined, at increased risk for infection or simply concerned about exposing themselves by traveling to a collection site. This approach will have a significant impact on helping people in New Jersey and across the United States get back to work as we will be able to monitor large numbers of people in a variety of locations.

"Being able to collect a sample for COVID-19 testing at home will have a major impact in terms of screening for COVID-19 in New Jersey and throughout America," Brooks continued. "Collecting a saliva sample at

home mitigates the risk of exposure needed to travel to a facility or drive through and is less invasive and more comfortable and reliable than sticking a swab up your nose or down your throat. Protecting both patients and healthcare professionals from any unnecessary exposure is of paramount importance and saliva home collection addresses almost all issues around testing quality, safety and availability."

The FDA emergency use authorization is the second obtained by RUCDR Infinite Biologics and its collaborators in recent weeks. The first was for a new collection approach that uses saliva as the primary test biomaterial for the SARS-CoV-2 coronavirus, which was the first such approval granted by the FDA and allowed health care workers to collect people's saliva at testing sites. Last month, RUCDR also launched a genetic testing service for the coronavirus that can test thousands of samples daily. With the new saliva tests and expanded collection strategy, that number can increase to tens of thousands of samples daily.

"RUCDR Infinite Biologics' pioneering research exemplifies Rutgers' commitment to addressing the most pressing global challenge we face," said Rutgers-New Brunswick Chancellor Chris Molloy. "By significantly increasing the number of people who can be tested every day, we are helping combat this pandemic and providing a way to move our communities forward. We are proud that Rutgers can be on the cutting edge of this achievement."

"Saliva testing addresses many critical issues associated with large-scale screening that is required to get people back to their normal daily lives," said Brooks. "Saliva testing is very important for symptomatic patients at home, so they can better determine how long it will be until they are no longer infectious and can safely return to their daily activities.

"And importantly, this new approval will help the Rutgers community directly by allowing for convenient and precision testing of faculty,

students and staff when the time comes for Rutgers to reopen the campus."

Provided by Rutgers University