New COVID-19 Saliva Swab Boosts Testing Capacity

SUNY Upstate Medical University

Testing is critical to prevent and contain the spread of COVID-19.

The U.S. Food and Drug Administration (FDA) issued an emergency use authorization for Clarifi COVID-19 on September 22, 2020.

> *The new, rapid diagnostic test developed by researchers at SUNY Upstate Medical University and Quadrant Biosciences in Syracuse, NY, has boosted SUNY's testing capacity twelve-fold -- to over 120,000 tests per week -- and will help communities across the country better pinpoint and contain COVID-19.*

Quadrant is an epigenetic diagnostics company that has a lot of experience in identifying human and microbiome

genetic material in saliva. Dr. Frank Middleton, associate professor of Biochemistry and Molecular Biology at SUNY Upstate, worked with Quadrant as co-lead investigator on the research behind its RNA diagnostic test for autism spectrum disorder (Clarifi ASD, which uses the same unique saliva collection kit). Middleton realized in March that some of that experience and knowledge could be used to create a saliva test to diagnose the COVID-19 virus.

Quadrant's Clarifi COVID-19 Test Kit uses the same saliva collection kit used in Clarifi ASD. This collection kit is unusual in that it has an integrated transport media that prevents degradation of the SARS-CoV-2 RNA prior to laboratory testing (thereby limiting "false negatives") and inactivates the virus (making the laboratory handling of the specimen safer).

Initially developed for individual testing, Clarifi COVID-19 was the third most sensitive test in the world. Quadrant successfully modified Clarifi COVID-19 to allow for pooling of up to 12 individuals without losing sensitivity. In the "pooled test" multiple samples are combined into a single "pooled" sample, which is tested for COVID-19. If the entire pooled sample tests negative, this means that all 12 people whose individual samples are included in the pooled group are presumed at the time to be COVID-free.

Now, thanks to SUNY Upstate and Quadrant's innovation, if the pooled sample tests positive, each individual saliva sample within the pool is quickly tested individually to pinpoint exact positive cases - without the need to collect a new sample, thus providing the ability to rapidly screen more than 20,000 samples a day in a single lab to identify the infected individuals.

The cutting-edge innovation has enabled SUNY Upstate and Quadrant to provide affordable, high-quantity testing across the entire SUNY system.

The FDA authorization makes this new, innovative test available for use throughout the U.S. by high-complexity clinical laboratories serving patients at physicians' offices, urgent care clinics and hospitals. According to Quadrant Founder and CEO Richard Uhlig, the company is already working with several laboratories within the U.S. and is in negotiations with others internationally.

"The ability to transfer Quadrant's innovative diagnostic platform to address the urgent need for COVID-19 testing solutions demonstrates the great value of strategic collaborations between academia and industry," said Matthew Mroz, director of Innovation and Partnerships at the Research Foundation for SUNY. "We are proud to have supported this effort by working collaboratively and swiftly with the research teams at SUNY Upstate and Quadrant to draft and file joint patent applications, and to negotiate various agreements including licenses, collaborative research agreements, and materials transfer agreements to enable the broad commercialization of Clarifi COVID-19."

SUNY researchers are shaping the future by producing more than 200 new technologies every year. Within SUNY's broad and rich research portfolio, special focus is placed on scientific and technological areas that have the potential to accelerate economic growth, drive social impact, and enhance human wellbeing. The RF works with business and industry, government agencies and other partners to move SUNY's ideas and inventions to the marketplace.

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