FDA authorizes sample pooling for SalivaDirect PCR COVID-19 test

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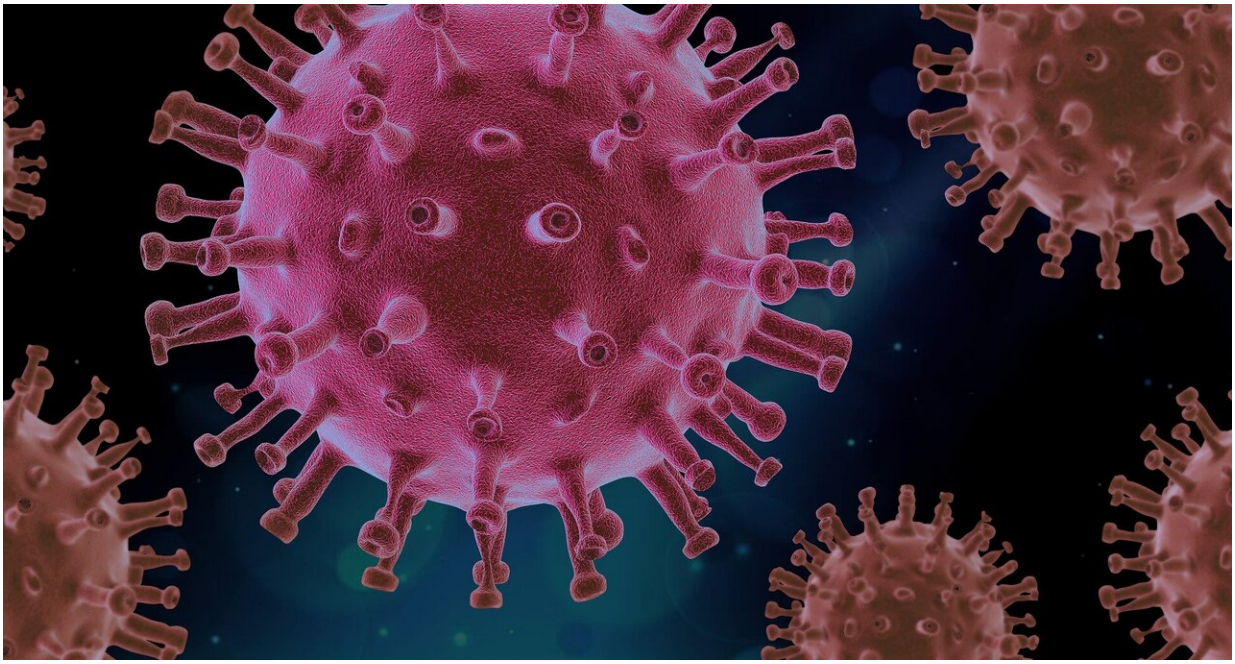

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The U.S. Food and Drug Administration (FDA) has authorized the SalivaDirect PCR COVID-19 test created by the Yale School of Public Health for use with pooled saliva samples.

Pooled testing allows labs to combine saliva samples from multiple individuals into a single tube and process the batch as a single test. This

approach maintains the clinical sensitivity associated with the real-time reverse transcription polymerase chain reaction tests—the gold standard for detecting SARS-CoV-2, the virus that causes COVID-19—and gives labs the ability to process the tests far more quickly. The FDA authorizes Yale-designated laboratories to use the SalivaDirect test to pool as many as five samples at a time for SARS-CoV-2 testing.

"As vaccination programs gain ground and help us protect against severe COVID-19 cases, we must remain cautious. Adopting frequent testing as a new public health habit will help keep us safe from infection and keep our schools, workplaces, and businesses open," said Anne Wyllie, principal investigator of SalivaDirect and research scientist at the Yale School of Public Health. "Sample pooling with SalivaDirect provides labs with an additional tool they can use to minimize testing materials, increase throughput, and report faster results."

SalivaDirect is one of only three saliva-based PCR tests to receive "emergency use authorization" (EUA) in the United States for the detection of SARS-CoV-2 in pooled samples. If a pool tests negative, all individuals in the pool are classified as negative for SARS-CoV-2, and no additional testing is needed. If a pool tests positive, the lab conducts additional testing to identify the positive individual(s) in the respective pool.

"Keeping our community of university students, staff, and faculty healthy and on campus depends on our lab's ability to detect SARS-CoV-2 infections. This enables individuals with positive results to self-isolate, seek care, and prevent further viral spread. SalivaDirect has been a mainstay for COVID-19 testing because it is economical, user-friendly, accurate, and has rapid turn-around times," said Suzanne Sandmeyer, professor of biological chemistry and director of both the Campus COVID-19 Testing Laboratory and the Genomics High-Throughput Facility at the University of California, Irvine. "This FDA clearance to

pool samples will further enhance our lab's flexibility to rapidly scale testing, helping us respond quickly to infection rate changes due to new virus variants or post-holiday surges as people return to campus from outside our community bubble."

SalivaDirect is an open-source RT-qPCR test designed to be streamlined, sensitive, and low-cost. Testing saliva with readily available reagents and equipment from multiple suppliers also eliminates the need for nasopharyngeal or nasal swabs, which have been prone to supply chain shortages. The ease of saliva-based testing lends itself to self-collection for all ages—keeping test site staff safer and reaching patient populations that may be less likely to comply with nasal swabs due to the associated discomfort.

SalivaDirect has been deployed to 142 lab sites in 39 states and over 2 million tests have been administered to date in the United States. The protocol was created at the Yale School of Public Health as an alternative to other testing methods for COVID-19 and it received an emergency use authorization from the FDA in August 2020.

SalivaDirect can be used for routine screenings of individuals without COVID-19 symptoms or for those suspected of having COVID-19. Samples can be collected in the presence of a trained observer or, for individuals 18 years old and older, in the comfort of one's own home without supervision using the SalivaDirect Unsupervised Collection Kit or SalivaDirect At-Home Collection Kit. Collected samples can then be dropped off at a collection site or mailed to a testing laboratory.

Provided by Yale University