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SALIVA AS A RELIABLE SAMPLE TYPE FOR SUSTAINABLE SURVEILLANCE AND OUTBREAK RESPONSE EFFORTS

The COVID-19 pandemic presented an unprecedented demand for diagnostic testing. Testing is essential for isolating infected individuals, contact tracing and epidemiological surveillance for public health countermeasures, but at times has been strained by inadequate infrastructure and supply chain disruptions. To overcome these challenges, we developed an open-source, low-cost, sensitive in vitro diagnostic assay in an effort to deliver equitable testing across the US.

SalivaDirect was developed as a simple diagnostic test by 1) eliminating collection tubes with preservatives, 2) developing clear self-collection instructions, 3) replacing nucleic acid extraction with a simple enzymatic step, 4) testing specimens in dualplex RT-qPCR, and 5) establishing a sustainable umbrella emergency use authorization (EUA) regulatory model. Around our mission to provide accessible and affordable testing, any qualified CLIA lab is welcome to test under the SalivaDirect EUA negating the need for an independent EUA or Lab Developed Test. This approach led to the formation of a national network of labs designated to test with SalivaDirect.

[View complete abstract on second page.](#)

Anne Wyllie, Ph.D.



*Research Scientist,
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As compared to the gold standard nasopharyngeal swab, Dr. Wyllie's work has identified saliva as a reliable sample type for the sensitive detection of *Streptococcus pneumoniae* (pneumococcus) in healthy older adults and more recently, SARS-CoV-2 in persons suspected of COVID-19. Improved detection of the pneumococcus has unveiled hidden reservoirs in older adults which holds importance when new vaccination strategies for preventing pneumococcal disease are being considered. For COVID-19, sampling saliva can alleviate many of the bottlenecks encountered in the mass testing strategies required to control continuing outbreaks. In an effort to address many of these issues, Wyllie validated and optimized saliva for SARS-CoV-2 detection and developed SalivaDirect: a simple, scalable and importantly, cost-effective method to help alleviate SARS-CoV-2 testing demands. Wyllie's SalivaDirect Initiative at the Yale School of Public Health remains devoted to providing public health guidance, advancing saliva diagnostics, and enabling the safe re-opening of communities worldwide.

February 2, 2023 • 3:30 p.m.

Location:
108 Watt Auditorium



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Introduction: The COVID-19 pandemic presented an unprecedented demand for diagnostic testing. Testing is essential for isolating infected individuals, contact tracing and epidemiological surveillance for public health countermeasures, but at times has been strained by inadequate infrastructure and supply chain disruptions. To overcome these challenges, we developed an open-source, low-cost, sensitive in vitro diagnostic assay in an effort to deliver equitable testing across the US.

Methods: SalivaDirect was developed as a simple diagnostic test by 1) eliminating collection tubes with preservatives, 2) developing clear self-collection instructions, 3) replacing nucleic acid extraction with a simple enzymatic step, 4) testing specimens in dualplex RT-qPCR, and 5) establishing a sustainable umbrella emergency use authorization (EUA) regulatory model. Around our mission to provide accessible and affordable testing, any qualified CLIA lab is welcome to test under the SalivaDirect EUA negating the need for an independent EUA or Lab Developed Test. This approach led to the formation of a national network of labs designated to test with SalivaDirect.

Results: Since receiving EUA on August 15th, 2020, 190 labs in 41 states have been designated to test using SalivaDirect. With over 7M+ tests performed, designated labs administer 36K+ SalivaDirect tests/day with a projected capacity of 228K+ tests/day. Reports of very few false-positive (8) and false-negative (5) results with low rates of sample rejection (0.62%) and invalid tests (0.38%) demonstrate reliable, effective implementation of the SalivaDirect assay across a diverse lab network. The collective expertise of the network guided the expansion of SalivaDirect protocol, with over 20 amendments in the last two years in response to lab needs. The SalivaDirect EUA now includes dozens of validated reagents and instruments for increased testing flexibility and supply-chain resilience. In collaboration with lab network partners, we verified test accuracy in asymptomatic individuals and developed unsupervised and at-home saliva collection kits for individuals aged ≥ 2 years. Remarkably, the lab network became a platform for sharing knowledge, expertise, samples and resources, which proved particularly important when responding to new variants.

Conclusions: The open-source SalivaDirect PCR test evolved into a nationwide lab network. Leveraging upon the upfront validation work performed by our team, labs could easily implement SalivaDirect into their workflow process. Together with our network we formulated an effective testing solution for local communities. The SalivaDirect assay has strengthened the public health response for a future pandemic and has laid the groundwork for others to build upon its research.

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