



COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #42

Thursday, *December 16, 2021, 12-1 PM ET*

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #42

This week's Diagnostics Evidence Accelerator meeting consisted of 2 presentation:

1. From Open-Source SARS-CoV-2 PCR Test to Broader Public Health Initiative (Dr. Anne Wyllie, Yale University)
2. Heidi the Hypothetical Patient (Susan Winckler and Dr. Carla Rodriguez- Watson, Reagan-Udall Foundation for the FDA)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One of Diagnostics Evidence Accelerator.

From Open-Source SARS-CoV-2 PCR Test to Broader Public Health Initiative (Dr. Anne Wyllie, Yale University)

SalivaDirect started as a PCR test to increase accessibility and now it is part of the public health initiative. Given the different PCR test hurdles (e.g., shortages, invasive, and uncomfortable) that were present at the beginning of the pandemic, the team looked into other methods of testing. One of these methods that they looked at was using saliva as a sample type to aid testing challenges.

In order to understand if saliva can be used as a sample type, Yale School of Public Health published data where they compared samples from a nasopharyngeal swab sample to a saliva sample. The finding showed a higher viral detection in the saliva sample compared to the nasopharyngeal sample. Additionally, since saliva is not a traditional diagnostic sample type, methods for swabs do not necessarily work on saliva. Therefore, saliva tests must be designed for saliva and if it is not properly collected, it can be difficult to work with. A comparison study was conducted that looked 54 RT-qPCR-based saliva and swabs. The findings showed that 69% found saliva to have greater or similar ($\leq 10\%$ difference) sensitivity and saliva detected an additional 10% of positive cases which were NP swab negative.

Through the learnings, the researchers developed SalivaDirect™ which is an extraction-free and dual-plex RT-qPCR. This test is non-invasive and less expensive test that circumvents supply chain disruptions. Figure 1 shows show how SalivaDirect isolates the virus.

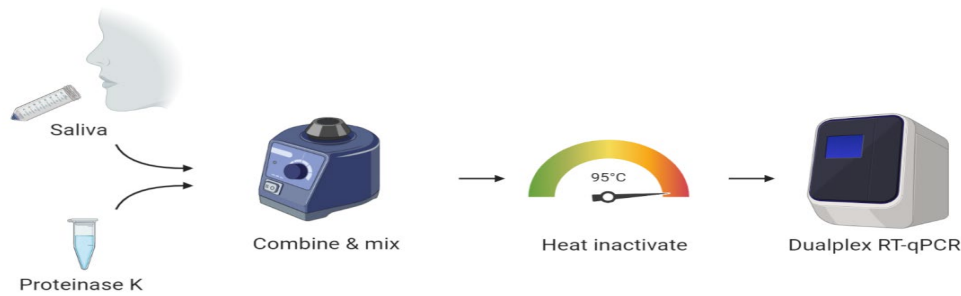


Figure 1: The steps to isolate the virus.

They validated the reagents and instruments for use with multiple vendors. This allowed them to use existing resources to keep the cost of the test down. This allowed them to maintain a high level of sensitivity. Their limit of detection is 3-12 copies/ μL for all combinations and is equal to or better than 38% of all EUA molecular tests, including the U.S. CDC RT-qPCR assay. They received EUA on August 20, 2020.

They were able to create a collaborative and growing network which expanded 155 labs in 41 states. They have established a Google group to address any questions that their labs will have. Anyone from this group was able to answer questions about testing. This allowed the research team to receive feedback on the test and protocol. They expanded their protocol to include additional information. In figure 2, the grey boxes is the initial protocol and the yellow boxes show how they have expanded their protocol.

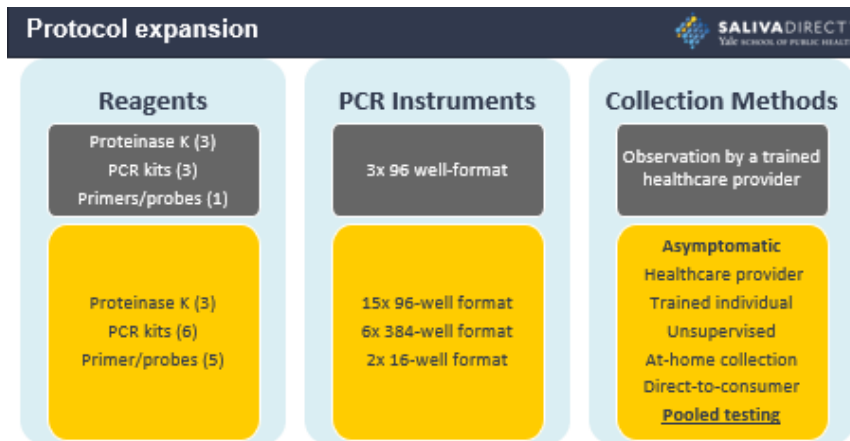
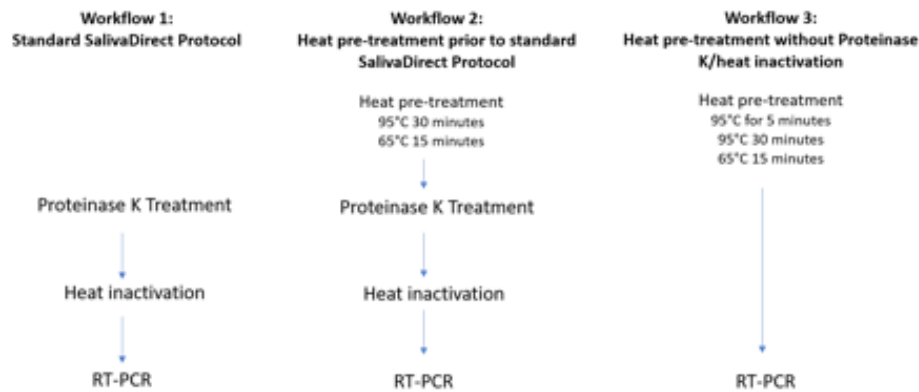


Figure 2: Protocol expansion. The grey boxes show the initial protocol and the yellow boxes show the expansion.

Since different labs had different needs, they changed the protocol and work flow for the labs. Figure 3 shows the protocol evolution in response to those needs.

Protocol evolution in response to lab needs



Safer sample handling, improved viscosity for easier pipetting

Figure 3: Protocol changes to address the different lab needs.

With the move from diagnostics testing to surveillance testing, Yale School of Public Health is in support of surveillance testing. Saliva based testing can be used for surveillance testing. Given the geographically diverse network of laboratories, there are additional research areas that we can look into for surveillance. One way to do this is using Ct values to monitor community spread. Even though surveillance testing is needed, lab-based testing is important for detecting and monitoring the new variants.

In support with the Rockefeller Foundation, SalivaDirect created a play book for school based surveillance testing to help schools understand their testing needs, mitigation strategies, detection, and vaccination requirements.

In April 2021, they had a successful K-12 testing program in Colorado. COVIDCheck Colorado served approximately 15 school districts where approximately 1,500 SalivaDirect tests/day were administered. Additionally, in Ohio State University (OSU), approximately 29,000 people/week and approximately 5,000-7,000 test/day are administered. Key lessons from the program from Ohio State University were

- Ohio State students returned to campus in the fall and have continued to attend without any major outbreaks;
- Ongoing surveillance allows rapid identification of cases and people they've been in contact with and move them into isolation or quarantine;
- SalivaDirect is has conducted 85% of COVID-19 tests in the state of Ohio; and
- OSU is testing at a faster rate than 10 states including Oklahoma, Mississippi, and New Mexico.

Heidi the Hypothetical Patient (Susan Winckler and Dr. Carla Rodriguez- Watson, Reagan-Udall Foundation for the FDA)

With the new development of tests, Heidi the hypothetical patient received a rapid antigen OTC test. However, the question remains how the data from her OTC test flows into her healthcare data. The data from the OTC is locked in a "box" creating a gap in the data flow. Therefore, there is a need to understand how to connect the data flow pipe from the OTC test.

If Heidi read her test via internet-connected technology, then with her permission there is an opportunity to decrease user bias in reading the results, report her data to the relevant health department, and report her data to her designated provider. Additionally, we would be able to capture specimen collected date, test result date, test result, and test name/device ID.

The Foundation is in the process of developing a project where the accelerator community can work together to understand the flow and connect the pipe. If the Accelerator Community has ideas on how we can connect the pipes, please reach out the FDA Foundation.

Next Steps

- Continue making data connections through the Evidence Accelerator and through www.EvidenceAccelerator.org.

Next Meeting: Thursday, January 20, 2021 12-1 pm ET