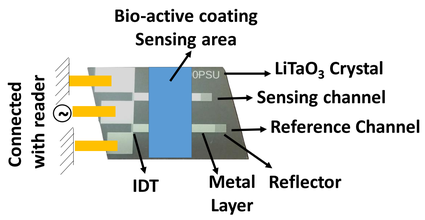
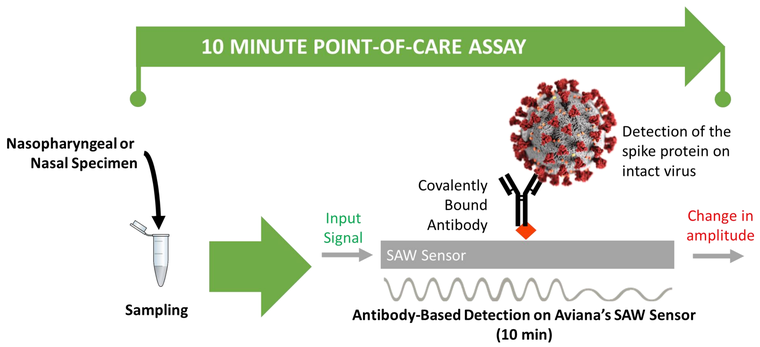
Abstract

- SARS-CoV-2 has devastated the health of millions of people worldwide and while this pandemic has stimulated many innovations in testing, none can detect the actual infectious virions but rely on RNA or protein detection
- Aviana (AMT) has developed a surface acoustic wave based (SAW) innovative, fast (<10 min), potentially cost-effective, and point of care (POC) platform that can detect infectious virions of SARS-CoV-2
- AMT's sensors are based on radiofrequency-based chips which detect mass changes bound to the chip surface; the chosen chip is ideal for detection of whole virus
- We present initial data on detection of SARS-CoV-2 virus using our Pegasus Digital Biosensing Platform (DBP) utilizing our RF chips

Sensor Design & Operating Principal



Top view of the sensor which consists of a sample channel and reference channel. Reference channel removes background signal and improves sensitivity.

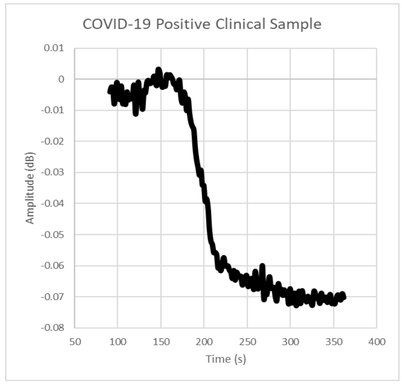


Side view of the sensor, showing the principle of SAW sensor. The property of the wave (amplitude) changes due to binding of the analyte when propagated through the sensing area.

Data Collection Process

- Spike monoclonal antibody obtained from Sorrento Therapeutics was immobilized to the surface of the sensor's sample channel.
- Limit of detection (LoD) was demonstrated using a BSL-2 safe SARS-CoV-2 pseudovirus from Integral Molecular.
- Sensitivity and specificity was determined using positive and negative COVID-19 clinical samples from nasopharyngeal specimens (NPS) in viral transport media (VTM) identified via an EUA RT-PCR test.
  - After a brief sample processing procedure, the sample was flown over the sensor in an enclosed fluid cartridge
- Binding of the virus to the antibody was determined by real-time changes in the amplitude of the SAW.

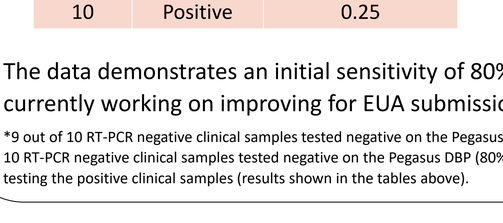
Real-Time Amplitude Shift



- The system reacts almost immediately after sample is added, amplitude change starts immediately (<30 seconds).
- Shown here is an example of the real-time amplitude change on the differential (sample channel response minus reference channel response) for a COVID-19 positive clinical sample.

Results – Limit of Detection Study

The RVP was diluted in VTM and tested on the DBP in duplicate through direct addition to the fluid cartridge.



Concentration: TU/mL	Concentration: Virus Particles	Replicate 1	Replicate 2	Average of Replicates
		ΔdB	ΔdB	ΔdB
0	0	0	0.005	0.0025
1000	30	0.01	0.01	0.01
2000	60	0.07	0.04	0.055
4000	120	0.025	0.03	0.0275
8000	240	0.175	0.3	0.2375

The data indicates that the DBP has an LoD of 30 virus particles per sample.

Results – Sensitivity and Specificity Study

COVID-19 Sensitivity Data – RT-PCR Positive Clinical Samples		
Sample No.	Pegasus DBP Response	Pegasus DBP Amplitude change (ΔdB)
1	Positive	0.03
2	Positive	0.04
3	Positive	0.04
4	Positive	0.075
5	Negative	0.0
6	Positive	0.025
7	Positive	0.04
8	Negative	0.0
9	Positive	0.025
10	Positive	0.25

COVID-19 Sensitivity Data – RT-PCR Negative Clinical Samples		
Sample No.	Pegasus DBP Response	Pegasus DBP Amplitude change (ΔdB)
1	Positive	0.4
2	Negative	0.0
3	Negative	0.0
4	Negative	0.0
5	Negative	0.0
6	Negative	0.0
7	Negative	0.0
8	Negative	0.0
9	Positive	0.03
10	Negative	0.0

The data demonstrates an initial sensitivity of 80% and a specificity of 80-90%*, which we are currently working on improving for EUA submission.

*9 out of 10 RT-PCR negative clinical samples tested negative on the Pegasus DBP (90% specificity) using our original sample processing method. 8 out of 10 RT-PCR negative clinical samples tested negative on the Pegasus DBP (80% specificity) using an optimized sample processing procedure used for testing the positive clinical samples (results shown in the tables above).

Disc

- Accurate and timely diagnos
  one of the obstacles to the c
  COVID-19, even in vaccinate
  variant now in circulation.
- In our preliminary studies, w
  detect the presence of infect
  platform.
- The platform is advantageou
  protein on virus particles an
  protein in the patient sample
  frequency of the SAW is opti
  bioparticles, such as virions a
- Our novel diagnostic platfor
  quantitative and real-time an
  fingerpick size sample volum
  rapid and accurate diagnosis

Con

- In this study, we have shown
  novel sensor platform has th
  detection of SARS-CoV-2.
- Given its potential, this syste
  used for many tests that cou
  accurate system.

Future

- Conduct a live virus study i
  analytical studies using rea
- Continue to obtain data on
  nasopharyngeal and nasal s
  delta variant
- Confirm the presence of vir
  the sensor's sample channe
  Microscopy
- Evaluate the system against

Ackno

We would like to thank Sorrento Therap
We also acknowledge that the views exp
reflect the official views or policy of the
work was partly funded by the DOD SBIR

6555 Sanger Road, Suite 200, Orlando, FL 32827 | 407-314-5577 | asingh@avianadx.com | avianamolecular.com