PROSPECTRAL™ DIAGNOSTIC DEVICE

FAST, ACCURATE AND HIGH-THROUGHPUT SCREENING OF COVID-19 INFECTIONS

Pattern Computer, Inc.; www.patterncomputer.com

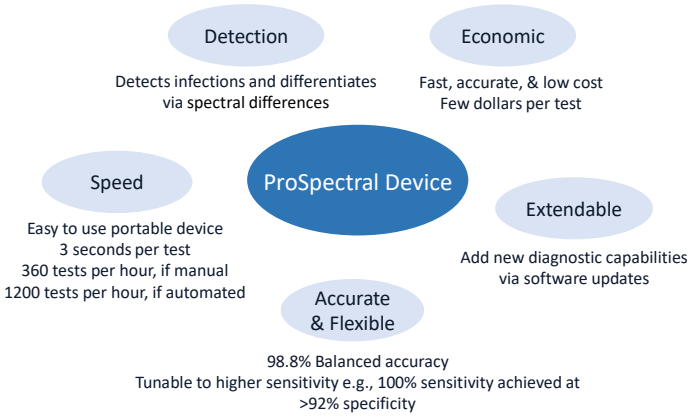
PATTERN COMPUTER®

BACKGROUND

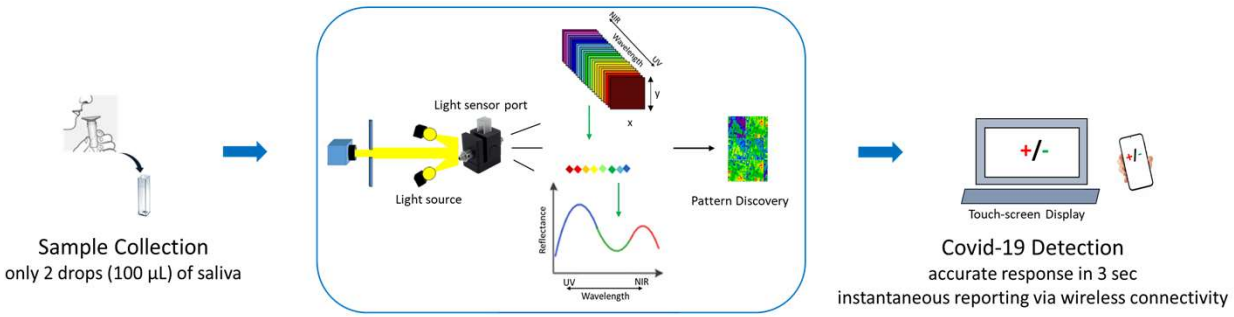
- COVID-19 has precipitated the deaths of >6 million people worldwide* and is the world's most expensive health crisis to date.
- Controlling its spread has been difficult due to the long pre-symptomatic period, the wide range of non-specific symptoms and the fact that it can be spread by symptomatic, as well as asymptomatic individuals.
- Rapid viral screening has become a crucial method to limit its spread.
- Immediate results, at point of contact are required for effective mass screening (i.e., TSA, public venues, schools…).
- Identifying asymptomatic patients early on can help prevent and control the spread of COVID-19.
- While RT-PCR has successfully been used in testing for respiratory diseases, in very early stages of infection (pre-symptomatic), RT-PCR results are limited by very low viral counts, potentially limiting effectiveness in mass screening of asymptomatic populations.
- Cost and availability of reagents for testing are barriers to mass screening.
- Therefore, there is an urgent need for rapid, reagent-free and on-site screening approaches for early and reliable detection of cases to control outbreaks and limit community spread of the disease.

(* https://www.statista.com/statistics/1093256/novel-coronavirus-2019ncov-deaths-worldwide-by-country/)

ProSpectral™ 300 Device

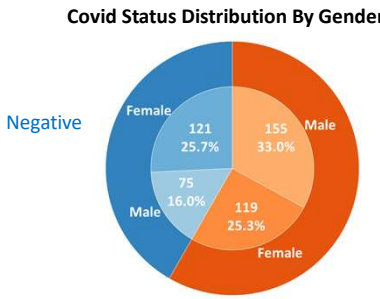


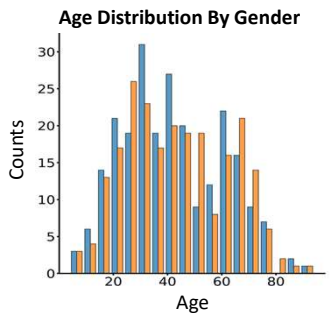
HOW DOES IT WORK?



DATA

- 470 previously frozen saliva samples provided by Cantor BioConnect
- **Negative** and **Positive** include symptomatic and asymptomatic samples
- Symptomatic range from 0 to 25 days from onset of symptoms

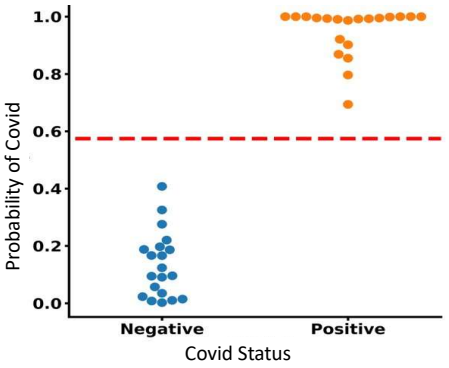




Negative/Positive for COVID determined by PCR

- Cantor BioConnect: Nasopharyngeal swab (CDC Method on ABI 7500DX)
- Los Alamos National Lab: saliva-based PCR test using FDA approved methods

PROOF-OF-CONCEPT: MODEL



Training on 430 samples
Test set: 20 Positive/ 20 Negative

Comparable to RT-PCR
Seconds to results
No reagents

Test POC Models multiple splits; < 1% error rate across 10x trials

CONCLUSIONS

- We have developed a line of light-based systems which can accurately detect a COVID-19 infected subject in subject's saliva, in three seconds.
- It identifies an active Covid-19 infection with 98.8% balanced accuracy.
- Only 2 drops (~100 µL) of saliva are needed. No reagents.
- The device can be also set to allow no infected individuals pass screening (zero false negatives), with 94% balanced accuracy (8% false positives to be forward to secondary methods.
- The device is designed to meet FDA 21 CFR 820 and internationally ISO 13485.2016 guidelines.