ProSpectral™

A Device for Detecting Disease State in 3 Seconds

Pattern Computer Inc.

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Abstract

As the world economy struggles to return to pre-pandemic activity, the inability to quickly determine the state of Covid infection in individuals continues to challenge schools, airlines, cruise ships, and large indoor venues as infectious variants surge through communities. With companies trying to re-establish their on-premises collaborations and work cadence, employees need confidence that their workplace is safe from infectious pathogens, and employers need to have confidence that they are not allowing infected employees to enter the workplace. The problem is that existing methods and techniques have not been able to provide an instantaneous test necessary to make this possible. Until now.

Pattern Computer Inc. (PCI) is currently in the later stages of developing a novel device, the ProSpectral™, that can accurately detect the metabolomic response to a disease state in 3 seconds. Given the current, fluctuating Covid-19 pandemic, PCI is now developing the models and cross-reactivity proofs necessary to pass the FDA Emergency Use Authorization requirements, while recognizing the data-gathering requirements for full certification.

Briefly described, the ProSpectral passes a broad-spectrum light source through a clear vial containing two or more drops of the test candidate's saliva. Light-source detectors capture the light-absorption pattern from the vial sample. The light-absorption pattern from the saliva sample provides a signature that is compared with a pattern model developed at PCI. When the test sample's light-transmission pattern is compared against the known model, *the results are as accurate as the existing gold-standard PCR test*[1]. A PCR test takes 15 minutes or more, requires disposable reagents, and typically costs $25–$55 per test. The ProSpectral is capable of processing 1,200 tests per hour and will be ready for limited testing by the end of 2022; production devices are expected in 2023. Cost estimates for the portable device are in the USD$40K range, with the cost per test in the ~$3–$5 range. The saliva sample can be discarded after the test, and no DNA data is collected during the test, thereby enhancing confidentiality.

Covid-19 is just the first disease the ProSpectral will detect. The device is simple enough for a layperson to use that it could be ubiquitous in hospital emergency rooms and patient admission areas for initial detection of other highly infectious diseases as well, before the patient even sees a nurse or a doctor. In regions with limited medical resources, this device could be extremely useful for accurately and quickly diagnosing a variety of diseases. As modeling of additional diseases (influenza A/B, tuberculosis, etc.) is completed, the device detection models can be remotely updated. In the current pandemic situation, the ProSpectral can enable businesses and communities worldwide to continue to function while having the ability to know where the infection is spreading and to rapidly determine who is infected.

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[1] A 9-month study with Los Alamos National Lab showed balanced accuracy over 98.5% based on fewer than 1,000 samples.

Introduction

Pattern Computer Inc. is a six-year-old company based in Friday Harbor, Washington, with offices in Redmond and San Diego. Pattern's mission is to *discover* patterns in high-dimensional datasets. Among the team's discoveries thus far is that using known broad-spectrum light sources with precision detectors creates a high-dimensional (very accurate) light-transmission pattern of the metabolomic response to Covid-19 infection in a test candidate's saliva. (PCI has filed a patent for this technique.)

Method

What makes this possible? First, the Pattern Computer team had to collect a significant amount of data on candidates who have tested both positive and negative for Covid-19. To accomplish that, the team built a prototype collection device (codename: *Barge*) that contained a broad-spectrum light source, a clear light-engineered saliva container (*cuvette*), and a precision light-collection sensor array, plus the associated power controllers, processing unit, and display. This device was provided to the US Department of Energy's Los Alamos National Laboratory to build up the collection of the positive and negative datasets.

The datasets were then provided to the Pattern team for processing with the Pattern Discovery Engine™ (PDE) to create a Covid-19 detection model, which was then validated against held-out (test) data. Pattern's results were as accurate as polymerase chain reaction (PCR) results. All these tests / results were based on frozen saliva sample data but cleared the proof-of-concept hurdle with the prototype Barge device.

The Pattern team has partnered with multiple companies in the US and abroad to collect fresh sample data to assemble the dataset samples required to build accurate model(s) based on fresh (vs. frozen) saliva data. PCI's initial partner continues to use a Barge to collect data, while other partner companies are using the next prototype, the *Outrigger*. (The production version of this device is named ProSpectral™.)

Device Design

The Outrigger is a more integrated prototype than the Barge, reducing exposure of the protected fiber-optic channel while enabling use of an interchangeable light source. It includes an angled LCD panel for easy reading from a standing or seated position.

The Outrigger also can use an external HDMI display instead of the internal display. The ProSpectral production device will include further internal component refinement.

Precision

The dataset itself is based on the nature of the light source and the
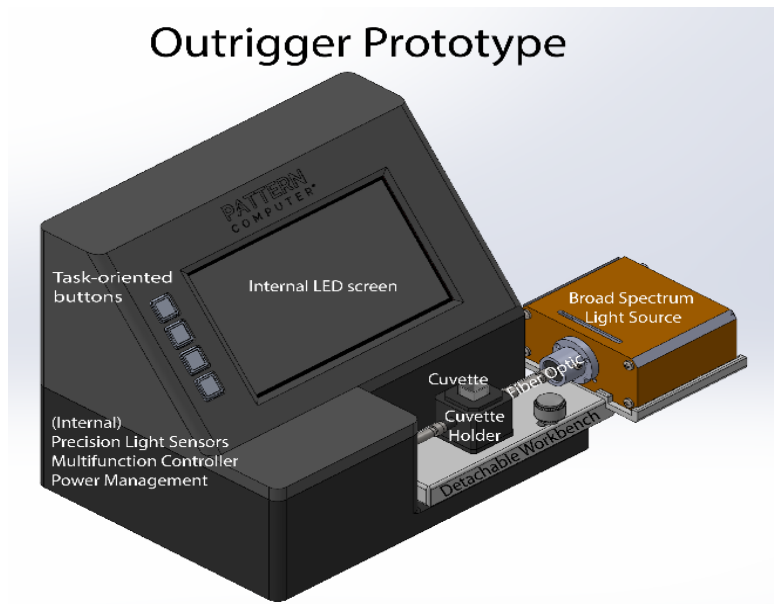
The ProSpectral™ device prototype "Outrigger"

pattern of light responses sensed by the Outrigger's array of precision light sensors. The cuvettes used, while commodity-priced, allow for the transmission of a broad spectrum of light, thus allowing for maximum sensitivity at the edges of the relevant spectral range. The resulting broad-spectrum light pattern reveals the light absorption response of the metabolites in the saliva. This configuration allows the Pattern Discovery Engine to theoretically detect a variation in a chemical bond length of 0.01 angstroms, or a 1-degree variation in the bond angle, which is beyond the capabilities of mass spectrometers. The ability to capture the light patterns with single-digit nanometer precision is a significant factor in the overall capabilities of both the device and the Pattern Discovery.

Process

The actual data-gathering process begins when the test subject provides 2 or more drops of saliva into a clean, disposable cuvette. The cuvette is perfect for the task at hand, being made of a clear polycarbonate material specifically designed for transmitting a broad spectrum of light. The cuvette is then placed in the cuvette holder. The data-collection process then begins with the activation of the light source, which carries light via a fiber-optic cable to one side of the cuvette. The light then passes through the cuvette and the saliva, where specific bands of the light spectrum are fully or partially absorbed by the metabolic response of the metabolites in the saliva sample. The resulting light is passed through the fiber-optic cable (on the other side of the cuvette) to an array of light sensors that capture the residual light pattern (both frequency and intensity).

In model building, the captured light-pattern data becomes a row in the dataset, *with the additional value of showing whether that instance of data is associated with a positive or negative (in this case, Covid-19) test*. When building the initial Covid-19 models, hundreds of samples were assembled into a dataset. A percentage of the data was held-out for the purposes of the test and validation sets, with the test set used to understand the accuracy of the model; some parameters for the model building may then be refined or tuned to improve accuracy. The produced models are tested for accuracy against the test set. When the model accuracy is above the acceptable threshold, it is then tested against the validation set to test if the model has been overfitted and therefore would not be acceptable for general use. If the results against the held-out validation data are accurate, then the model is deployed.

Individual Results

In production, the collected sample data is tested against the known model, and the results are presented to the output screen as positive or negative. If the sample does not produce a usable light pattern, the screen will display an error and request a retest using a new cuvette and saliva sample. Depending on the machine configuration, the local ProSpectral operator will see the results displayed on the device screen and can take appropriate steps should the results be positive. The device is then ready to receive the next dataset.

Higher Throughput, Anonymous User ID

In usage scenarios where high-volume throughput is desired, the ProSpectral has USB ports that could support a QR or barcode scanner accessory to capture a paired user card with the cuvette, which can be scanned to anonymously map the user to the test result. The anonymous ID and the test result can be displayed on a large digital display at, for example, an event entrance to allow patrons passage into the protected venue. Similarly, employee IDs can be mapped to the cuvette QR / barcodes, which can then

be recorded should the company or controlling agency require that test records be kept for government agency / health department purposes.

"Octopods"

The ProSpectral's design is flexible. While the development of the model itself is computationally challenging, the work of the device is relatively easy – comparing the light pattern of the sample against the known model. This is a sub-second process. *Thus, an individual ProSpectral device with its precise light sensors can serve as a shared "Octopod" device*, supporting up to eight lanes for people providing test samples to Octopod test-collection devices with individual light sources, digital QR / barcode scanners, cuvettes, and cuvette holders, with a fiber-optic connection to a data aggregator back to a single ProSpectral processing unit for final sample determination. This type of configuration reduces overall cost of the solution – requiring only one unit (or two, for backup) to support a high-volume demand, such as the entrance to an airport screening location, event center, arena, or school / university, to proactively prevent individuals with active Covid-19 infection from entering the venue. *One ProSpectral unit can process up to 1,200 samples per hour.*

Rapid Automated Feeders

An alternative to the multi-lane, Octopod approach is the implementation of a rapid, automated feed system whereby the (capped) cuvettes with the attached QR codes are fed into a collector system that captures and carries them through the ProSpectral optical system for scanning and analysis, providing the results on a digital display similar to that of the Octopods. This would likely be the preferred approach where the highest throughput is required using multiple lanes with 1,200 samples per hour (per lane) in continuous, full use.

Auditing, Recording, or Delayed-Access Strategies

Organizations, businesses, and governmental agencies are subject to different requirements. In cases where access to an event must be anonymous, a random cuvette can be associated with an individual for perhaps only 1 minute from screening to event admittance. (Patrons may prioritize individual freedom and not want "Big Brother" tracking their attendance at an event.) In other instances, such as workplace entrances, government screening locations, or border areas, tracking the individuals with their test results – and perhaps an employee ID, SSN, or other known reference – may be required. The ProSpectral can record the results to a SQL or other well-known database for auditing, recording, or delayed-access purposes. This information could be integrated with an employee-access or full-height turnstile gate-access control system. People could test for Covid-19 daily, and access to the building would be granted for the next 24 hours (allowing for a greater distribution of times of day when employees could be performing testing). Similarly, large events could include screening where attendees clear the detection process, then gather in the mezzanine or other apron area around the event hall prior to the event before entering the venue via a turnstile, etc., after showing the scanned QR / barcode on their phone (which would check against the database entry to validate entry).

Mobility

Because the ProSpectral is portable (the size of a lunchbox and under 11 pounds) and can be powered off a battery source, it is well-suited for remote situations and events. Production crew such as film crews, roadies, and other entertainment-industry staff can be tested daily in remote locations, keeping them healthy and minimizing exposure to infection. Event planners for remote-location events and the like can still have the information and results necessary to keep the event team and participants

informed of their health status and quickly take the necessary actions to prevent a super-spreader event.

Markets

The ProSpectral device in its full capabilities is expected to be able to detect any human disease based on a variety of inputs, including blood, saliva, and/or urine. With its capped system, given that the device uses light passing through the fluid, there is no DNA collection or direct contact with fluids. Red and white blood cells may need to be removed from blood samples prior to analysis to allow the transmission of light, but the signal response will still be present in the plasma.

In the transitional Covid-19 pandemic era, ProSpectral has broad markets in industries in which people need to congregate for extensive periods in relatively close quarters. This includes manufacturing / assembly plants, meat- and food-processing plants, mining, entertainment, sporting events, and many forms of travel (planes, trains, cruise ships, ferries, etc.). Schools from elementary school through universities have been significantly negatively impacted by Covid-19. Perhaps the most significantly impacted are grades K-12, as the students' need for and growth from social interaction and development are critical during these years. At the same time, schools need to make every attempt to keep their faculty, staff, and students healthy, while managing to have in-person classes for their students' social development, interaction, and overall mental health.

Another very advantageous aspect of the ProSpectral device is that it does not use or require any reagents, which are hard to find in emergent-disease scenarios and can be subject to supply-chain disruptions. Furthermore, many of the testing materials targeted toward a specific disease need to be manufactured, and there are inherent delays in the public-health response to these emergent, yet time-critical, life-and-death situations. The ProSpectral has the advantage of being able to dynamically update the models for detecting new diseases and new strain variants. The key to this effort is collecting new data to build updated models, which requires partnership with domestic and international health agencies.

Integrated Programs (Licensing)

Pattern Computer welcomes requests to take the ProSpectral device components and embed the system in other equipment to provide a unified screening platform for ease of use and to keep the amount and size of screening equipment to a minimum. "Powered by ProSpectral" branded equipment would utilize the same quality of hardware, simply integrated into a different form factor. Should custom hardware design work be required, the Pattern Computer team has its own internal hardware design team to address both the physical and electronic customizations required to meet the demand, be it a tight form factor, ruggedization, or weatherproofing.

Pricing

Individual ProSpectral units will be available in 2023 for sale or for lease, with attendant per-test fees adjusted accordingly. The basic per-test cost is estimated to be in the USD $3–$5 range, depending on:

- The number of different disease models selected for disease detection testing
- The backend services the customer would like PCI to support
- Whether the customer purchased the one-time Covid-19 model
- Whether the customer has an active subscription in which the models are periodically updated to maintain and/or increase their accuracy as the Covid-19 virus mutates and variants become known

- Monthly volume of tests performed
- Whether the customer is participating in Pattern Computer's Data Builder program

Competition

Why can't – or don't – other companies do this? As described above, Pattern Computer's proprietary Pattern Discovery Engine accurately discovers patterns in big data. Using this engine, PCI can discover the patterns in absorbed light as part of the metabolomic response to broad-spectrum light stimulation. Pattern Computer has filed a broad patent describing this novel approach. With enough sample data, it is expected that PCI potentially can create accurate models for all types of disease. Other companies, conversely, have developed accurate tests specifically for Covid-19, using reagents and other methods that entail creating enough copies of the sample DNA to make it possible to detect the virus.

Summary

Pattern Computer's portable ProSpectral device is the only device capable of detecting a Covid-19 infection – in 3 seconds – as accurately as PCR testing. It requires no reagents, does not capture DNA as part of the test, and each test uses only a disposable polycarbonate cuvette. The ProSpectral can quickly and efficiently be deployed in communities, in general does not require a medically licensed operator, and is the size of a lunchbox. For larger-scale deployments, the ProSpectral can conduct 1,200 tests per hour and can support a multiplexed, multiple-lane test configuration (imagine airport screening lanes) or use a mechanically fed auto-loader. In all use-cases, the cuvette can be identified with a QR / barcode matched with the test subject.

The ProSpectral is in the later stages of development at this time, and Pattern Computer is involved with the gathering of live data at locations in the US and internationally. The primary need currently is to complete gathering of the test data to effectively build the models for Covid-19 based on live samples, as well as to garner the cross-reactivity testing data required by the FDA with regard to influenza A, influenza B, or RSV.

Most important, the ProSpectral detection system is based on a model developed and deployed by Pattern Computer. As such, it can quickly be updated in the field as new variants of Covid-19 appear. As part of this process, the ProSpectral is expected to be able to accurately identify influenza A, influenza B, and RSV, with future updates as well. Furthermore, as Pattern Computer gains access to new data for diseases – such as measles, tuberculosis, and malaria – new models will be available from an expanding library of disease models.

The ProSpectral device delivers a new capability of disease detection. Able to identify Covid-19 infections, and in the future an expanded array of diseases, this device is coming to market at a critical time, as countries, schools, and businesses around the world need to have a way to return to pre-pandemic economic, academic, and industrial models.