PATTERN COMPUTER®

Disrupting Disease Detection

ProSpectral™

Executive Summary

In 2019, the world came to realize how globally interconnected we all are, as we watched COVID-19 invade our communities without regard for borders, religion, or political beliefs. It also became clear how unprepared our interconnected world was to address a highly virulent pandemic. As a result, we are currently faced with the reality of substantial viral loads in the global population and dealing with the many variants as mutations evolve.

How can we better prepare for future unforeseeable viral attacks, quickly deploy broad-scale testing tools, and identify impacted communities to curtail spread as much as possible? We need a disruptive technology – one that uses different methods which provide immediate, real-time responses to mutating diseases and are free from the need for DNA replication primers or continually updated, specific antigen materials.

With over 900 million infected in China in January 2023[1] and over 4 million deaths in India alone[2], the number of potential mutations grows. Global health, global economics, and political stability are all at risk. The GDPs of major economies have declined in these years largely due to quarantines, lockdowns, and shuttered industries. The travel industry effectively shut down. Schoolchildren have suffered from lack of social growth, interaction, and in-person communication with their teachers. Mental-health impacts to our youngest generations are still being measured.

We must be ready – with a more proactive, more scalable, and more cost-effective approach – to detect and identify these new virulent diseases as part of a pandemic preparedness strategy. It will take years before the variants of COVID-19 finally settle out, and existing methods have known inherent problems and/or limitations, including:

- PCR/antigen testing takes at least 15 minutes for a result, PCR often longer.
- PCR/antigen testing reagents need updating based on viral mutations.
- PCR testing requires large, complex, expensive equipment and specialized staff.

New devices are needed that:

- Provide fast, accurate results
- Can be pre-staged in the field
- Do not use any expiring reagents
- Can be kept current with the latest infectious models via timely, remote updates
- Can provide reliable daily, centralized reporting to local health organizations

Pattern Computer's ProSpectral™ instrument is one such highly innovative device. Quickly and with the accuracy of a PCR test, it can detect whether an individual is infected with a disease in only 3 seconds, as opposed to a few hours – or even days – with PCR tests. It uses no chemical or shelf-life–limited reagents; its only requirements are small polycarbonate cuvettes and two drops of saliva. ProSpectral's science, based on advanced mathematical analysis of light patterns, will also enable devices in the field

[1] https://www.bbc.com/news/world-asia-china-64258799
[2] https://cgdev.org/publication/three-new-estimates-indias-all-cause-excess-mortality-during-covid-19-pandemic

to detect a growing number of respiratory (RSV, influenza A/B) and other diseases over time, through simple software updates. It is expected that ProSpectral tests will cost only a few dollars per test, whereas PCR tests typically are in the range of US$15. Training to use the device takes less than an hour and does not require specific medical licensure. The ProSpectral device is also small, light, and can be battery-operated – ideal for fast and remote deployment to a local or global hotspot.

The Science

Let's look at the two testing methods in use today: the PCR test and the antigen test.

PCR (polymerase chain reaction) tests employ a common laboratory technique wherein specific short segments ("primers") of genetic material are copied millions of times to create enough material for molecular and genetic analysis. Fluorescent dyes are attached to the DNA strands to provide a marker of successful duplication of the viral DNA strand. The cycle is repeated 20-40 times to determine if there is enough amplification of the viral DNA to suggest a positive test, indicating (in this case) a COVID-19 infection. The cost of a PCR test can range from US$15 to US$40, and it can take anywhere from a few hours to a few days, depending on cost and demand, to receive the result.

Antigen tests detect specific viral antigens in a specimen and typically provide results in 15 to 30 minutes. These tests are less sensitive than PCR tests, and a single negative result does not rule out infection. For example, a recent study analyzing 152 different results found that antigen tests of persons who were in fact COVID-positive were only 72% accurate for persons showing symptoms; just 58% were accurate for those with no symptoms.[3] Antigen tests typically cost US$8 to US$20 per test.

ProSpectral™

In 2022, Pattern Computer announced ProSpectral, its testing device. Based on its Pattern Discovery Engine™–derived models, ProSpectral can identify, with the accuracy of a PCR test, whether a person has COVID-19 – but unlike the PCR test, it can perform this test in 3 seconds rather than a few hours or days. Additionally, the ProSpectral test does not require any reagents and generally costs only a few US dollars per test.

ProSpectral's diagnostic result is based on the spectral detection of metabolic responses to host infection. The device captures a high-resolution "fingerprint" of the response to infection. This fingerprint is then compared against a known, validated model to determine whether the person the sample was taken from is infected. In addition to detecting COVID-19, ProSpectral is expected to be able to detect infection in persons with other well-known diseases that may flare up around the world, given increasing populations of people who don't or cannot vaccinate (including children). Examples of such diseases include measles, tuberculosis, Marburg virus, and asymptomatic COVID-19, even at the early stages of infection.

Disrupting the Diagnostic Space

It is a fundamental shift in technology itself that enables this level of diagnostic task. Pattern Computer takes a completely new approach. It does not try to perform DNA replication millions of times to create enough sample material to identify specific DNA patterns and detect the fluorescence of the target material; nor does it identify a specific antigen in the live sample. The differences between the novel,

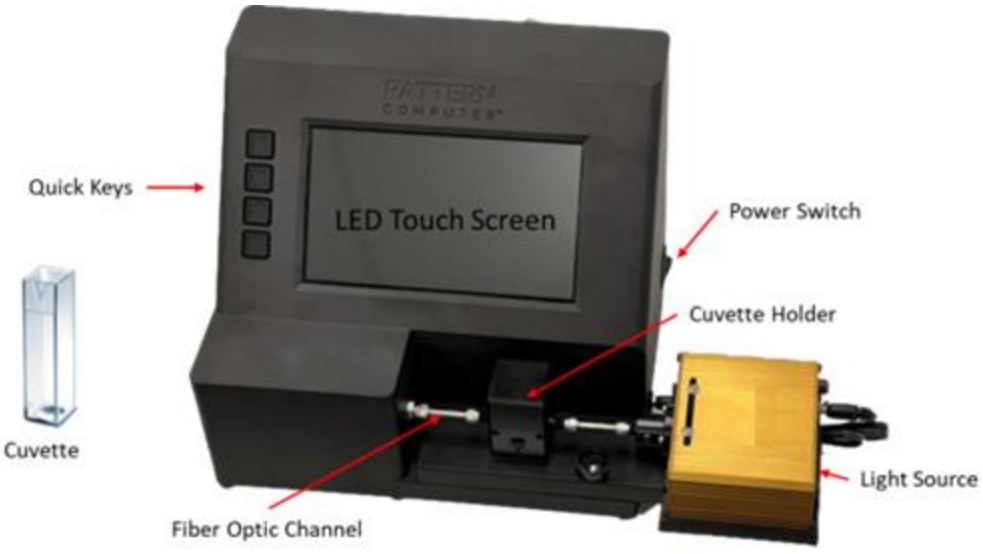
[3] https://www.cochrane.org/CD013705/INFECTN_how-accurate-are-rapid-antigen-tests-diagnosing-covid-19

light-based “fingerprint” of a healthy person and that of a person infected with COVID-19 provide a high level of detail. Light-based metabolomic fingerprints of healthy people are different from those infected with COVID-19, which is also different from the pattern of those with RSV, for example.

In essence, ProSpectral creates an entirely new space for accurate, high-performance diagnostic testing which can be conducted on an industrial scale and also be dynamically and securely reprogrammed or updated with the latest models in a matter of seconds. As COVID-19 mutates over time and different strains come to the fore, these dynamic models are updated with the information on the most recent variants. As a result, the accuracy of the model improves over time with larger and more diverse training datasets.

This is all possible because of Pattern Computer’s Pattern Discovery Engine and the company’s insight into using *light-based metabolomic fingerprints* (patent pending). This system can also distinguish between the various subtle pattern differentials in the data. That is Pattern Computer’s specialty. It is also important to stress that no medical professional or other specially trained person is required to operate ProSpectral. The standalone device is the size of a lunchbox, with a reclined screen for easy readability. The cuvette holder sits on a “workbench” that is engaged in the front of the device. The cuvette holders may also be positioned away from the central ProSpectral device for servicing multiple lanes of testing, with barcodes attached to the cuvette holders to distinguish among the test subjects.

Most exciting about this novel, disruptive method of testing is that it has the potential to be applied to *any disease* with a metabolomic optical response. Imagine the benefits of having one of these devices in a hospital admissions ward. After the prospective patient is asked to provide two drops of saliva, and before their ID is even entered into the system, the *private* response to the admitting staff member may be that this person has influenza A, and perhaps is pregnant, as well. ProSpectral could similarly be used at a local doctor’s office, a company’s onsite medical facility, or a center for diagnostic screening of potentially infectious diseases. No special testing chemicals or reagents. No specially trained staff (other than for privacy / confidentiality of results). The only item needed is the disposable polycarbonate cuvette.



ProSpectral™

Using ProSpectral, once ~1,000 samples of (e.g., COVID-19) infected patients are available to train and test a model, that model can be distributed electronically to all ProSpectral devices to enable them to diagnose the disease as accurately as PCR testing, in only 3 seconds.

Another advantage of ProSpectral's use of the cuvette with no reagent required is the removal of supply-chain issues, which could otherwise be an obstacle to essential early and rapid virus identification. The cuvettes can easily be stocked and remain in storage for years, ready for use – whereas specific reagents may have a short shelf life and need a pre-planned distribution network and timely buildup of the specific reagents in order to meet needs as they arise. ProSpectral needs no such real-time supply-chain management.

In an uncertain world, we need flexible systems that can dynamically pivot to unforeseen needs. With ProSpectral, no contact with the patient's saliva is required, and the sample can be discarded once it has been passed through the device (i.e., no DNA is collected). A single ProSpectral device may have more than one disease model available – for example, it may have one for COVID-19 variants and one for RSV. These models can be securely and remotely updated to keep them current with the latest variants. It is anticipated that additional models will be available, with the eventual expectation of a library of validated models, including influenza A, influenza B, potentially tuberculosis, and the Zika virus. As these are mathematical comparisons, additional tests can be run in less than 1 second per test.

Essential Customers

Hospitals have an absolute need for fast, efficient, accurate, and cost-effective means of assessing employee health. They are already understaffed and overburdened trying to recover from the excess costs incurred during the height of the COVID-19 pandemic, prior to the availability of vaccines. Yet still today, many hospitals must test all staff on a daily basis to make sure none are carrying the virus and potentially spreading it to patients, many of whom have lowered or compromised immune systems. With hospital staffing levels already under pressure, the fact that ProSpectral does not require medically trained staff means that resources currently allocated for processing COVID-19 PCR testing within the hospital would be freed up, and staff would not need to arrive 20-30 minutes early for testing to be allowed to work with patients. With ProSpectral, that test would take 3 seconds.

In our interviews with pediatric hospital staff and administrators, they highlight how much easier it would be to gain saliva samples from children rather than attempting to get nasal samples. They also cite ProSpectral's ability to quickly narrow in on the disease at hand (when present) and distinguish whether that patient should be quarantined. This is particularly significant for small urgent-care facilities with low staffing levels.

Today, Pattern Computer is engaged with hospitals in gathering the data necessary to build these accurate models and provide the hospitals with accurate, affordable, daily testing to protect their staff,

patients, and respective communities. Furthermore, universities in the United States are looking for ways to track viral transmissions in their faculty, staff, and student populations. Pattern Computer is actively working with one university to use this disruptive technology to offer daily testing in its university community. Innovation leaders such as these institutions are working with these new technologies to better serve both themselves and their communities in a scalable, cost-effective manner.

Scalable Technology

Pattern Computer has also focused on the scalability of the ProSpectral devices. As mentioned earlier, each device can perform a test in 3 seconds, or 1,200 tests per hour. With a multi-lane "Octopod" configuration, the device can support as many as eight separate testing devices connected to a single ProSpectral unit – allowing up to nearly 10,000 tests per hour. These types of configurations would be particularly useful at sporting events / arenas, airlines / airport screening, schools / universities (daily screening), and cruise ships. There are also areas of work in close quarters where it is important to know if co-workers may be infected – for example, mining, athletics, open-space workers (tech), and public modes of transportation, including trains and buses.

Central Reporting

We have established that hospitals, universities, and commercial organizations such as cruise ships or those with workers in open spaces could benefit from having a top-down view of disease spread. Depending on the collection process, the results could be anonymized, or they could be tracked by employee or student number. Then healthcare scientists could review where those people may be clustered in their work locations or lunchrooms, or perhaps their transit routes to and from places of business. Centralized reporting allows health scientists to understand potential vectors of transmission and take appropriate action. It also allows for longitudinal studies of disease spread throughout the population and assists in identifying falsified reports. As this information can be made immediately available via a central datastore, a monitoring algorithm can look for significant jumps based on different groupings (e.g., work locations, lunchrooms, transit) to assist in identifying potential transmission vectors as soon as possible.

Summary

ProSpectral presents a disruptive method of disease detection that is highly accurate, highly scalable, cost-effective, and uses no reagents. The detection mechanism is based on the metabolomic fingerprint differential of the saliva of a healthy vs. an infected patient, created when subjected to broad spectrum light. The device can detect a broad range of diseases with a metabolomic response due to its highly sensitive sensors and Pattern Computer's unique Pattern Discovery Engine. The only requirement is polycarbonate cuvettes in which to collect and present the saliva samples for testing.

Each device can perform 1,200 tests per hour and can either be configured with an automatic feed system or use multiple lanes for moving people through quickly using remote light benches / cuvette holders connected to a central ProSpectral device. Having devices positioned in the field prior to a virus outbreak and being able to remotely update the detection model to the latest version is critically important to having a quick understanding of where the disease is spreading in the target population, and hence, to rapid response.

Operating ProSpectral does not require a trained medical professional, as the test involves no chemical preparation, no reagents, and no swabbing of nasal passages. (Biological precautions against cross-contamination and infection do need to be followed.) The device can be battery-powered in a mobile configuration as well, wherever testing is needed onsite at a remote location.

Pattern Computer has demonstrated these capabilities using frozen saliva samples. The company is currently engaged with multiple hospitals and one university in building the live sample models and validating those results. Discussions are ongoing with other universities and related organizations in the European Union and within the UK.

In an interconnected world in which preparedness is key, no other innovation has ProSpectral's ability to distinguish between multiple subtle pattern differentials in data, in addition to the advantages described above. ProSpectral has already proven to offer solutions for now and the future that are both more practical and more compelling than any other innovation on the market today.