PROFILE

Name: Specific Diagnostics
Location: Mountain View, CA
Founded: 2011
Website: specificdx.com

CHALLENGE

Convert scent-related data to visual data to identify the deadly bacteria that cause bloodstream infections and the antibiotics to treat them…in just hours, rather than days.

SOLUTION

Create a device that combines an incubator, computer processor, a touch-screen display and the Epson® Perfection® V600 scanner to support the launch of a mass-produced, practical, reliable, and affordable diagnostic solution for the most expensive condition treated in U.S. hospitals.

Fast and Specific Diagnoses

Epson Scanning Technology Helps Medical Startup Diagnose Bloodstream Infections in Hours Rather Than Days

Four years ago, Ray Martino and his partners found themselves in a unique position to help people around the world.

They learned that a technology they had invented might be used to quickly and accurately identify bacteria that cause bloodstream infections, along with the antibiotics best suited to treat them. If they could make this work, they might help to save millions of lives each year.

Today their company, Specific Diagnostics, is testing a tool that promises to do just that. A key component in its success is photo scanning technology from Epson.

Timely Treatment

Martino explains that bloodstream infections can lead to the onset of sepsis. According to two hospital studies, sepsis contributes to one in every two to three hospital patient deaths[1]. According to a 2013 report, it is also the most expensive condition treated in US hospitals, costing more than $23 billion annually[2], a real challenge for a cost-strained healthcare system. A study by the National Center for Biotechnology Information suggests that, globally, as many as 5.3 million patients may die from sepsis each year[3].

Fast treatment is crucial, but difficult to get right. Death from sepsis increases by six percent every hour without effective antibiotic treatment[4]. Yet, despite the life and death urgency, current practices require at least two days to identify an effective antibiotic. “No one can wait that long, so doctors have to treat with powerful broad-spectrum antibiotics that are too often ineffective,” Martino explains. Predetermining the right antibiotic is getting tougher, however, because there are so many strains of antibiotic-resistant bacteria.

“Specific’s new product, Reveal AST/ID, simultaneously identifies the bacteria and tests the effectiveness of various antibiotics in an average of four hours,” says Martino. “The patient gets effective treatment within hours, rather than days.”

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"The potential of this new technology has the attention of health organizations around the world," he adds. "The National Institutes of Health have provided more than $10 million in grants to help Specific's research; CARB-X, a public-private partnership dedicated to accelerating antibacterial research, has granted up to $3.5 million to help with the development of the technology."

Bacteria and Scent

Specific Diagnosis was founded by three friends with related interests: Dr. Paul Rhodes, an expert in neural computing and the science of how the brain processes smells; Dr. Kenneth Suslick, a world renown chemist at the University of Illinois; and Martino, a businessman who had been Chief Technology Officer at Motorola Solutions.

About 10 years ago, they began discussing an idea that seemed to have commercial prospects."As human beings," Martino explains, "we primarily experience the world through our sense of sight, but many animals relate to the world largely by scent rather than sight." The small, volatile molecules that produce smells tell animals a great deal about the world they live in.

"Even as humans, we use our noses to judge ripeness, quality and spoilage," he adds. "Likewise, in the manufacturing of food—coffee is a good example—producers have developed sensitive, and very expensive, instruments to judge when the beans are ready to harvest."

"Because scent is so important, we asked ourselves, 'How can the world not have a core sensing technology to measure these volatile chemicals that's as cheap and simple to use as a camera?' As we have a camera to relate to the world with sight, we need a device to relate with scent."

The partners founded their company to develop such a technology, starting from the insight that if they could convert scent-related data to visual data, it would be easy to process with existing tools. "Computers were already good at recognizing visual patterns, so all we had to do was produce a visual pattern for each combination of molecules, each with a distinctive scent."

Dr. Suslick knew a large number of chemicals change color when exposed to a volatile molecule. "He invented a paper

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sensor array about the size of a postage stamp, with 10 to 100 little sensor dots printed on it," Martino explains. "These sensor dots change color when exposed to a particular molecule, for example, benzene or formaldehyde. If you have a hundred indicators, you get a 'fingerprint' of scent, very analogous to the way olfactory receptors work in an animal's nose."

Next, they had to capture the color changes. "We considered various cameras, but the reality is, no matter how good the camera, you get distortions from the lens and reflections from a flash. On the other hand, the best photo scanners give you a completely uniform image, better than the best camera we could buy." They began experimenting with various scanners.

By 2014, they had a workable sensor array, a library of color-changing chemicals and a prototype that could input the color changes into a computer, but still had not determined the first application on which they could focus their efforts.

"A microbiologist we met said, 'You know, bacteria stink, and experienced microbiologists can identify bacteria species by their unique scent. If you could use your technology to identify bacteria causing infections, you could do a lot of good in the world.'"

The partners spent the next four years developing their technology as a diagnostic instrument for hospitals.

Building an Instrument

In developing this instrument, Martino recalls, the company had two main challenges. They needed to choose a set of chemicals best-suited for identifying the bacteria that cause bloodstream infections, and they needed to create a buildable instrument to grow and identify the bacteria cultures. The instrument would consist of an incubator, a computer processor, a touch-screen display, and a scanning component.

In developing prototypes, Martino says, "We evaluated all of the scanners on the market and found Epson® was the best for our needs. The color performance, illumination and resolution are amazing for such small, low cost devices."

Of the various Epson models, they decided on the Epson Perfection® V600, the smallest of the Epson photo scanning line. The V600 offers 6400 x 9600 dpi resolution[5], 48-bit color depth and a maximum scanning area of 8.5" x 11.7". Its ReadyScan® LED light source is durable and requires no warm-up time. A full-size, full-color scan takes just six seconds. “It’s true that Epson makes better and faster models,” Martino explains, “but this scanner had everything we needed.”

Next, they tested the scanner rigorously and were very pleased with the results which exceeded well-beyond their expectations. “We ran it continually to estimate its mean time between failures,” he explains. “It turned out to be very reliable: ten times better than its published specs.”

By 2018, Martino and his partners were ready to approach Epson about buying their photo scanning technology in a form they could build into their production instruments. “Still, we weren’t sure how they would react to our requests,” he recalls.

“Each year, hospitals and clinics around the world order about 300 million diagnostic tests to identify these bloodstream pathogens. Ours would be a mass-produced instrument, practical, reliable and affordable.” Specific would need the Epson technology together with strong support and a low price.

Martino says he called on Epson group product manager Sean Gunduz and healthcare business development manager Jerry Tarrant to explain his requests. “I was pleasantly surprised how responsive they were.”

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Hours Not Days

In addition to the instrument, the Specific team needed sensor arrays tailored to identifying bacteria, and they needed a way to test the effectiveness of antibiotics on the particular bacteria strains they found.

To identify the bacteria, the company developed a product they call Reveal AST/ID, which uses a small plate with 96 wells. Each little well contains a drop of what started as a human blood sample together with an antibiotic. With 96 wells many different antibiotics can be tested at different strengths.

The Reveal AST/ID instrument with the Epson scanning technology scans each tray and compartment every ten minutes to detect the changing color of the sensor array. “By measuring the sensor array color response with the Epson scanning technology, we can determine which antibiotics will be effective and kill the bacteria and which antibiotics will not work.” Martino says.

“Together, the sensor array and optical scanning are so sensitive that the system can determine which antibiotics the doctor should prescribe in four hours, compared to current practice that takes two days,” shares Martino. “This is a tremendous improvement that can save many lives.”

“In traditional tests, the lab is looking at the opacity of each compartment, and the cultures must grow thick enough to produce a visual contrast with those that don’t,” Martino explains. “Our sensors, on the other hand, can pick up parts per billion emitted by the bacteria, so we can get reliable results in just four hours.”

Clinical and Pre-Clinical Testing

Tarrant, Epson's healthcare business development manager, says Epson photo scanning technology can be used in various ways in the healthcare field. "We work with several healthcare partners to provide rapid, yet reliable solutions to transmit quality patient health data that enables these partners to verify patient identities for initial intake and ongoing care management, as well as to safely and securely store data in electronic medical records," he explains. He encourages healthcare manufacturers, integrators and providers to contact him about their needs.

At this writing, the Reveal AST/ID products are in pre-clinical testing, with Reveal instruments installed in hospitals to compare its results with traditional laboratory results. "So far, no medical decisions are being made using the results of our tests," Martino explains, "but that will change when we finish clinical testing and hopefully receive FDA clearance." He expects clinical testing will be complete in a year.

If successful, Specific Diagnosis, and its founders, believe they will be able to save lives and make a positive difference for human health around the world.

"We're really glad to have the relationship with Epson," Martino says. "We know it is a company we'll be able to rely on for many years to come."

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[1] https://jamanetwork.com/journals/jama/fullarticle/1873131

[2] https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.jsp

[3] https://www.journalofinfection.com/article/S0163-4453(17)30193-7/fulltext

[4] https://journals.lww.com/ccmjournal/Fulltext/2006/06000/Duration_of_hypotension_before_initiation_of.1.aspx

[5] Optical Resolution is the maximum scan resolution of the CCD elements, using the definition of ISO 14473.

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