



## Hemex Health Brings Portable Malaria and Sickle Cell Disease Testing to India, Africa

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NEW YORK – With a pair of rapid assays in hand, Portland, Oregon-based startup Hemex Health will soon launch a malaria test through its subsidiary in India, while it collaborates with Novartis for a sickle cell diagnosis and treatment in Africa.

Cofounded in 2015 by Patti White, now the firm's CEO, and biomedical device developer Peter Galen, Hemex's flagship technology is its point-of-care Gazelle instrument, a portable, battery-operated, cartridge-based diagnostics system with two testing ports.

After evaluating IP from dozens of academic centers, they were drawn to two technologies developed at Case Western Reserve University by researchers Umut Gurkan and Brian Grimberg. Hemex licensed these technologies in 2016, and advanced them into the Gazelle diagnostic device, White said.

One port on the Gazelle is a reader that can detect substances with magnetic properties using opticomagnetic imaging. The other is a new spin on gel electrophoresis that rapidly runs very small reaction volumes on microchips and uses computer vision and deep learning to enable monitoring the reaction in real time, providing a quantitative readout.

Data can be stored on the Gazelle or taken off with a USB drive. It is also Wi-Fi-, Bluetooth-, and GPS-enabled, so test results can be easily geotagged and tracked through the cloud.

The instrument was purpose-built to be rugged, require minimal training to operate, and be affordable for low-resource settings, White said. Specifically, the cost of the reader is "about the price of a Smartphone," or between \$800 and \$1,200, while the cartridges range from \$1 to \$3.

### **Malaria and sickle cell disease**

The Gazelle currently has a menu of malaria and sickle cell disease (SCD) assays. It can also quantify hemoglobin variants, and the firm has an anemia test in development as well.

The malaria test takes one minute to run using the opticomagnetic port on the instrument.

Malaria-causing plasmodium parasites accumulate iron-bound heme metabolites while munching on blood cells, which they excrete as a substance called hemozoin. This

magnetic, toxic [biocrystal](#) is thought to be part of the disease etiology in plasmodium's hosts.

White said that most rapid diagnostic tests for malaria target an antigen called histidine-rich protein 2, or HRP2, which is only expressed by *P. falciparum* and can be mutated so that it becomes [undetectable](#) using standard RDTs.

Hemozoin, however, is excreted by all plasmodium species, so the Gazelle test can detect the difficult-to-detect strains that infect humans, namely *P. vivax*, *P. knowlesi*, *P. ovale*, and *P. malariae*. This is similar to a recently-described [breathalyzer](#) malaria test that boasts the advantage of detecting all species as well.

Hemozoin is also found in a helminth worm parasite that infects 250 million people each year in Africa, [Schistosoma mansoni](#), and in the "kissing bug" insect vector [Rhodnius prolixus](#) of Chagas disease-causing *Trypanosoma cruzi*. A few rapid diagnostics for [shistosomes](#) and [Chagas](#) in vectors exist, but they do not appear to rely on hemozoin detection.

After partnering with the Tata group in India for market research, Hemex created a subsidiary there called HemexDx, and has already received regulatory clearance for the malaria test. The SARS-CoV-2 pandemic delayed the launch initially, but the firm now expects to roll out the malaria test in India later this year.

The microchip-based, automated electrophoresis port in the Gazelle, meanwhile, can separate hemoglobin groups by charge, and then identify and quantify them using optical analysis, with results and interpretation displayed on the instrument in eight minutes, White said.

Meanwhile, blood cells with a mutation in the hemoglobin beta gene are prone to adopting a sickle-shaped conformation, leading to sickle cell disease, or SCD, and this can be detected with the Gazelle as well.

It is believed that sub-Saharan Africa accounts for 80 percent of the SCD burden in the world, and the autosomal recessive condition can [lead to](#) anemia, increase the severity of infections, and cause periodic episodes of intense pain. More than 1,000 babies are born each day carrying at least one copy of the sickle cell genomic trait, and half of those with the disease will die before age five, most commonly of severe bacterial pneumonia. Overall, SCD is thought to lead to the death of an estimated [500 children per day](#) worldwide.

As is the case with many so-called neglected diseases, there is a simple, effective, and relatively inexpensive treatment regimen for SCD already available.

Babies diagnosed with SCD early could be given a pneumonia vaccine, followed by daily oral penicillin until they are five years old to prevent infection, and hydroxyurea to minimize blood clots, a regimen that reduces SCD mortality by as much as 90 percent, according to Kwaku Ohene-Frempong, an [esteemed](#) SCD expert who leads the Sickle Cell Foundation for Ghana, and who is "very enthusiastic about Hemex's Gazelle platform for SCD testing.

In Ghana, about 2 percent of the country's 950,000 babies born each year have the disease, Ohene-Frempong said, while in Republic of Congo the rate is as high as 3 percent.

This rate contributes to the under-five mortality in a major way, he said. "Unfortunately, because most of these babies are not tested, when they die, people don't know sickle cell disease contributed to their death," he said.

The Gazelle could have particular utility in the field, particularly in clinics that see babies and vaccine centers, Ohene-Frempong said. The immunization rate in Ghana for a score of

vaccine-preventable diseases is a remarkable 98 percent, even in rural areas, a testament to educational campaigns and informed consumers who now demand that their government provides this service. Unfortunately, this has not been the case for [newborn screening](#), Ohene-Frempong said, and in some years Ghana's program struggles to get the funding it needs to test even a small portion of babies.

For lab-based newborn screening, Ohene-Frempong said the majority of tests are run using instruments and assays from PerkinElmer, which has the advantage of high throughput.

Petra Furu, general manager of reproductive health at PerkinElmer, said the firm is heavily involved in the development of SCD newborn screening programs in Africa and recently [partnered](#) with the American Society of Hematology (ASH) to take part in their Africa SCD Consortium. The firm is also part of the World Bank Sickle Cell Disease Coalition, with seats in two subcommittees.

Through collaborations with industrial partners, healthcare policy makers, and global and local NGOs like Ohene-Frempong's, PerkinElmer is working to increase awareness and education, and "to make accessible and affordable best-in-class newborn testing and treatment," Furu said.

In particular, PerkinElmer is aiming to build upon collaborations and donation programs to expand implementation of a universal SCD screening program, Furu said, adding that the firm's Migele gel electrophoresis solution is "designed to offer the best quality and flexibility at the lowest price" for labs in Ghana and elsewhere.

Ghana has begun expanding its newborn screening program, in part with support from the Clinton Health Access Initiative and the Gates Foundation, Ohene-Frempong said. The PerkinElmer instrumentation currently used by the program is relatively inexpensive, he said, but at the moment the assays cost \$5.50 to screen each baby. He estimated that to make the Ghana newborn screening program universal and permanent would require \$8 million per year.

Outside of the lab, there is certainly a place for Hemex's point-of-care strategy as well, he said.

"There are millions of children in Africa between the ages of six months and five years, which is when the mortality from [SCD] is highest," Ohene-Frempong said. These children could be tested with the Gazelle at routine vaccination appointments, for example, and have their status determined rapidly.

Besides getting infected children onto lifesaving treatment, diagnosis could also prevent over-treatment. Ohene-Frempong said that children under five in Ghana who present to a hospital with symptoms of even a mild infection, like an earache, are often admitted and put on intravenous antibiotics until a lab-based SCD test can come back, because infection-related death in SCD patients can happen so extremely quickly.

"If the Hemex machine was in the ED, and the nurse just stepped off and 10 minutes later came and said the child is a carrier of the sickle cell trait but does not have the disease, he gets an oral antibiotic and goes home," Ohene-Frempong said.

Separately, a lateral flow SCD test called HemoTypeSC from Silver Lake Research showed high sensitivity and specificity for SCD detection in an [American Journal of Hematology](#) evaluation published last year, and did an immunoassay test called SickleScan from BioMedomics in [Pediatrics](#), and these could potentially have an impact as well.

However, the leading cause of death in children infected with plasmodium is acute anemia, Ohene-Frempong said, so a combined SCD, malaria, and anemia rapid diagnostic

instrument has the potential to make an outsized impact. Overall, the Gazelle is, "a lifesaving machine," Ohene-Frempong said.

## Partners, posters, and pipelines

With its diagnostic test for SCD, Hemex is working with Novartis, which has developed a monoclonal antibody treatment for the disease called Adakveo (crizanlizumab) that was cleared by the US Food and Drug Administration this year for once-a-month infusion. A representative at Novartis said that the firm [partnered](#) with Hemex through the Novartis Biome program, a digital innovation lab that aims to empower health tech companies.

The Swiss-based pharmaceutical firm has also recently expanded its Africa SCD program with three memoranda of understanding with the ministries of health of Uganda, Tanzania, and Kenya. It is now collaborating to develop a comprehensive approach "that makes screening, diagnosis, and treatment available, accessible, and affordable for patients," and that promotes scientific research, training and education, the representative said, adding that as part of the overall effort, the Novartis Biome team has worked with Hemex Health to accelerate the development of the Gazelle.

To date, Hemex has been funded by angel investors and strategic investors, White said, and has won four grants from US National Institutes of Health since 2017 totaling more than \$6 million.

In addition, Hemex was awarded \$300,000 in a Vodafone Wireless Innovation contest to pilot the Gazelle in Nigeria along with a mobile app that links patient data with an electronic medical record system. The firm also [won](#) \$100,000 in a recent NIH Technology Accelerator Challenge for a non-invasive version of the hemozoin malaria test that uses a finger cuff in partnership with medical device firm Medtronic.

Hemex is also working with the Foundation for Innovative New Diagnostics on malaria studies, White said. Its Chief Medical Officer, David Bell, is the former program head for malaria at FIND who previously spent time scaling up malaria diagnostic with the World Health Organization.

In terms of US regulatory submission, White said Hemex has had pre-submission meetings with the US Food and Drug Administration and plans to submit a 510(k) in the first quarter. "They encouraged us to submit our malaria test, because right now there is not an accurate test for *P. vivax* approved by the FDA," she said, adding that the firm will subsequently submit its electrophoresis test.

Hemex is currently seeking collaborative partners in assay development to further expand its test menu as well as with a larger global player to help disseminate the technology.

So far, studies of the instrument show it to be quite accurate. Results of five research projects using the Gazelle were recently presented at the American Society of Tropical Medicine and Hygiene Annual Meeting, for example, where the Gazelle was shown to be more sensitive than rapid diagnostic tests in detecting *P. vivax* in a study conducted in the Brazilian Amazon, while a study of samples from Brazil, Cambodia, and India showed the test had a limit of detection that was six times lower than RDTs.

The malaria test was also shown to be capable of detecting and discriminating different plasmodium species in an evaluation in India. In East Malaysia it was shown to effectively detect *P. knowlesi*, and researchers at the National Institute of Research in Tribal Health in India presented data at ASTMH comparing standard SCD diagnostic methods to Gazelle's SCD test in 949 patients, and found the Gazelle to be highly sensitive and specific, as well as being faster and less expensive, and requiring less training to operate.

Preliminary results for Hemex's in-development anemia test were presented at the American Society of Hematology meeting late last year, showing 100 percent sensitivity and 92 percent specificity for anemia detection, and 100 percent accuracy for hemoglobin variant detection, in a sample of 46 patients.

Going forward, for the automated electrophoresis port on the Gazelle, Hemex is developing a test for anemia that is essentially a software upgrade that can be delivered to the device through the cloud. It is also pursuing a test for HbA1c, a proxy of average blood sugar levels used to detect diabetes. And the firm is adding fluorescence to the electrophoresis port so it can add immunoassay products, White said. Hemex is also pursuing running magnetic nanoparticles-based immunoassays in the opticomagnetic port.

"We're focused on making the Gazelle able to do as many tests as possible, in the developed world in addition to the developing world," White said. "As we've seen with COVID, there is a lot of value in having a test that can be taken remotely."