

### A new weapon in the fight against sickle cell disease

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# Technology behind this week's launch of Hemex Health's "Gazelle" diagnostic platform was developed by researchers at Case Western Reserve University

A technology developed initially at Case Western Reserve University is behind the global launch (https://www.devex.com/news/optimized-for-the-underserved-a-new-diagnostic-test-built-for-low-income-settings-97456) this week by a Portland, Oregon, company of a new, faster and low-cost diagnostic test for sickle cell disease (SCD).

The announcement by Hemex Health comes just in advance of <u>World Sickle Cell Disease Awareness Day (https://www.sicklecelldisease.org/get-involved/events/awareness-month-and-world-sickle-day/)</u> on Friday, June 19.

SCD is the most well-known among a group of inherited blood disorders, affecting about 100,000 people in the United States and about 20 million worldwide, according to a 2018 National Institutes of Health (NIH) statement (https://www.nih.gov/news-events/news-releases/nih-launches-initiative-accelerate-genetic-therapies-cure-sickle-cell-disease) announcing the National Heart, Lung, and Blood Institute (https://www.nhlbi.nih.gov/) (NHLBI) Cure Sickle Cell Initiative (https://curesickle.org/).

More than 500 children with SCD die daily (https://www.globenewswire.com/Tracker?data=T-\_1J
QDiOOLBTwsG5dTozFQYmRLOOq39fZkGyTAJ\_9uUB2jSvxlJFclsi\_ysx5JpwZUo03QdmkVsvAWlfXetZ9jJFlplzQjDaFZ0bKFxBT5b3uck4j6Qz5FMlsEiKDzaW8SpclkfQzrył
85b\_unXl4Uu7ponqKMu3G\_Xms5VslaRur5n) around the world because of lack of access to early diagnosis and treatment.

"With improved access to inexpensive diagnostics and cost-effective care, children with SCD could lead relatively normal lives to achieve their highest potential," Kwaku Ohene-Frempong, president of the Sickle Cell Foundation of Ghana, said in the Hemex Health news release.

Hemex Health officially launched Gazelle after its sickle cell disease test was given regulatory approval in India and Ghana, with other country registrations pending, according to the Hemex news release (http://www.globenewswire.com/news-release/2020/06/17/2049261/0/en/Gazelle-Diagnostic-Platform-Designed-for-Low-Resource-Settings-Integrates-Miniaturized-Technologies-with-Al-to-Transform-Disease-Screening-and-Diagnosis.html).

The portable diagnostic platform combines proprietary microchip electrophoresis technology, which is a miniaturized version of the traditional blood test, with artificial intelligence.

Gazelle also includes a test for malaria, also developed at Case Western Reserve by a team led by Brian Grimberg, an assistant professor of pathology, international health, infectious disease and immunology at the School of Medicine's Center for Global Health & Diseases.

Hemex is seeking the same regulatory approval for malaria testing as it has for the sickle-cell tests and is working to develop tests for anemia and <u>COVID-19</u> (https://www.devex.com/focus/covid-19).

#### Case Western Reserve's role

"This is a special day for me and for my lab members," said <u>Umut Gurkan, the Warren E. Rupp Associate Professor</u>
(<a href="https://engineering.case.edu/emae/faculty/umut\_gurkan">https://engineering.case.edu/emae/faculty/umut\_gurkan</a>) in the Department of Mechanical and Aerospace Engineering in the Case School of Engineering.

Gurkan leads a university team that also recently was awarded up to \$3.7 million from the NHLBI to assess emerging genome editing-based therapies being tested for SCD at leading U.S. research universities and hospitals.

Concurrently, his team was working on the electrophoresis technology used in the Gazelle platform. It was invented in Gurkan's Case Biomanufacturing and Microfabrication Laboratory (CASE BML) in 2014, he said.

"Our lab at CWRU worked on the initial prototype development, proof-of-concept testing and initial clinical validation with support from Clinical and Translational Science Collaborative (CTSC (https://case.edu/medicine/ctsc/)) and Case Coulter Translational Research Partnership (https://engineering.case.edu/ebme/cctrp)," Gurkan said.

Initial clinical studies of the sickle-cell technology were done in 2014-16 in collaboration with the Sickle Cell Program at University Hospitals Cleveland Medical Center, which then expanded to Nigeria, India and Thailand. The results were published this year in the Analyst journal of the Royal Society of Chemistry. (https://pubs.rsc.org/ko/content/articlehtml/2020/an/c9an02250c)

Hemex Health licensed the microchip electrophoresis technology from CWRU in 2016, Gurkan said.

"And since then, we worked closely with Hemex in making this product a reality," he said, citing support from "many individuals, organizations and funding agencies, primarily NHLBI, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/research-funding/research-programs/small-business)) and National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/grants-contracts/small-businesses)) small business programs."

Gurkan also said "invention of this technology at CWRU specifically played a key role in its success in translation," pointing out that Case Western Reserve is in the top 100 nationally for utility patents. (https://academyofinventors.org/wp-content/uploads/2020/05/2020-2019-top-100.pdf)

"This speaks to the attention given to protection of intellectual property, patenting, licensing, and commercialization efforts by the <a href="https://case.edu/research/faculty-staff/technology-transfer">CWRU Technology Transfer Office</a> (<a href="https://case.edu/research/faculty-staff/technology-transfer">https://case.edu/research/faculty-staff/technology-transfer</a>) (But by <a href="https://case.edu/research/about/meet-our-staff/michael-haag">https://case.edu/research/about/meet-our-staff/michael-haag</a>)," Gurkan said.

## Rapid malaria diagnostics

While Gurkan is the primary investigator from Case Western Reserve regarding sickle cell disease, Grimberg is the head of the research into the malaria diagnostics.

"It has been nearly 10 years since I shone a laser pointer through my sunglasses and at a test tube containing malaria-infected blood and saw that when we brought magnets near the blood sample that the laser spot on the far wall became dimmer and smaller," Grimberg said. "All our steadfast efforts and continued funding stemmed from this moment to the present where the idea of inexpensive rapid malaria diagnostics has been brought into the world where it can diagnose people."

Both Grimberg's malaria project (in 2016) (https://thedaily.case.edu/medicine-physics-collaboration-wins-federal-patent-humanity-award/) and the Gurkan's sickle cell diagnostic tool (in 2018) (https://engineering.case.edu/news/umut-gurkan-wins-2018-patents-humanity-honorable-mention-hemoglobin-scanner) won U.S. Patent and Trademark Office Patent for Humanity Awards.

# The 'smartphone of diagnostics'

"Gazelle is 'the smartphone of diagnostics' because it integrates powerful consumer electronics, digital storage and wireless communication into a portable, multi-disease platform," Hemex Health's co-founder and CEO Patti White said in the company's release. "Our mission is focused on using these powerful, affordable technologies to improve diagnostics for those living in low resource settings."



Brian Grimberg

Hemex worked with endemic country health care experts to rethink diagnostics for low resource settings. With this input, Hemex engineered Gazelle to make a highly accurate test for SCD and other hemoglobin variants widely available for at risk populations.

To learn more, read about Hemex strategic partnerships (https://www.globenewswire.com/Tracker?data=wcF3F
Pjfa3K56MGcufpKEllF2561J9hCLz7nkkjox1cDOGgPjbMaCsYFtK8Mn\_NWSrFReGlqn79ssG9U4YgzuWtVxKgP0fC3eL5CLowzoy41YAKCG3CR7L9cARzj\_-K) and watch a video of Gazelle (https://www.globenewswire.com/Tracker?

data=xXgkpvyZgzBuvl0peb\_FwTVZEaPzx1qT7v62vAlegE6zAtLlJLVbTqbv1NTiNP4djiZlmOmbvdTHP-3A9Xsb2g==).