

## NEWS EMBARGO for June 16, 2020 0300 EDT

### **Gazelle® Diagnostic Platform, Designed for Low Resource Settings, Integrates Miniaturized Technologies with AI to Transform Disease Screening and Diagnosis**

- *8-Minute, Low-Cost Diagnostic Test for Sickle Cell Disease (SCD) Among First Approved Tests*
- *Includes a One-Minute Malaria Test with Solutions to Follow for Other Health Priorities*

[Portland, Oregon, Mumbai, India / 17 June 2020] Officials from Hemex Health in Portland and Mumbai were joined by global health thought leaders in anticipation of World Sickle Cell Day by launching the company's Gazelle® Diagnostic platform. Gazelle features a Sickle Cell Disease (SCD) test that has CE Mark and regulatory approval in India and Ghana with other country registrations pending.

"We describe Gazelle as 'the smartphone of diagnostics' because it integrates powerful consumer electronics, digital storage and wireless communication into a portable multi-disease platform," said Patti White, Hemex Health's Co-Founder and CEO. "Far too little research and development addresses the need for improved diagnostics in low resource, remote settings. Our mission focuses on using new powerful, affordable technologies to give these clinicians the diagnostic tools they need to provide better outcomes."

#### **Sickle Cell Disease – An Overlooked Global Health Problem**

Sickle Cell Disease presents an enormous health challenge for many regions in the world. More than [500 children with SCD die every day](#) because of lack of access to early diagnosis and associated treatment.

Professor Kwaku Ohene-Frempong, President of the Sickle Cell Foundation of Ghana and Program Coordinator for the National Newborn Screening Program for Sickle Cell Disease, estimates that currently fewer than 4% of babies in Ghana are tested for SCD because of the high cost to the public health service. "Many children die young of complications like bacterial infection or acute anemia, with their parents and healthcare workers never knowing the underlying cause to be sickle cell disease," said Professor Ohene-Frempong. "However, with improved access to inexpensive diagnostics and cost-effective care, children with SCD could grow to lead relatively normal lives and to achieve their highest potential."

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### **User Input Drove Design of Affordable, Accurate SCD Testing Solution**

Hemex wanted to design a targeted solution with user input from low resource countries to make testing for SCD and other hemoglobin variants widely available for at-risk populations. The diagnostic is built around the company's proprietary microchip electrophoresis technology – a miniaturized but more advanced version of traditional electrophoresis, that both identifies and quantifies many hemoglobin variants. "Because clinicians are familiar with electrophoresis, they have confidence in Gazelle's results," said Umut Gurkan, Associate Professor at Case Western Reserve University and inventor of the technology. "Analysis and interpretation are automated using artificial intelligence, making Gazelle usable by health workers of all levels of experience."

Prior to starting development, Hemex solicited input from health care workers, clinical experts and purchasing decision makers worldwide. Tata Elxsi, a Hemex partner in India, conducted an Indian multi-state market research project on Gazelle. "We heard from clinicians that they liked the technological approach and the price point. Also, there were many advantages to being able to complete the test in minutes during the patient visit," said Suhas Tamras, Global Head of Medical Devices, Tata Elxsi, Pune India.

"Based on all the feedback we collected, we designed a portable device that's highly accurate, low-cost, and works in hot, humid and dusty environments. We found that users can always charge their cell-phones, and so we made this compatible with Android cell phone chargers," said Peter Galen, Hemex's Co-Founder and Chief Innovation Officer. "We also added local and Cloud based digital storage to help busy clinics with record keeping and as an easy way to print out a report to give to the patient during the visit."

### **Collaboration with Novartis Biome**

Novartis, a leading developer and provider of SCD treatments, is actively developing access programs for SCD in Sub-Saharan Africa. Gazelle was selected as a partner product through its innovation accelerator, the "Novartis Biome."

"Gazelle gives us the ability to diagnose and treat thousands of children in Africa who would have otherwise died or lived with severe complications. This is the kind of technology that makes a clear difference on day one," said Robin Roberts, Co-Founder, Managing Director and Head of Strategy at Novartis Biome.

### **Distribution Partnership with Bio-Rad Laboratories**

Gazelle will be distributed exclusively in India and other key regions by Bio-Rad Laboratories of Hercules, CA. Bio-Rad has a distribution presence in over 130 countries and is a major player in hemoglobin variant diagnostic test products.

### **A One-Minute Malaria Test Also Available, Solutions for COVID-19 and Anemia in Development**

The low-cost diagnostic platform also includes a sensitive test for malaria that delivers results in about a minute. It is highly sensitive for *P. vivax* infections, which can be difficult to detect. The malaria test also has CE Mark, and regulatory review in India is underway.

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The development of a COVID-19 test for the platform was announced by Hemex in April, and the company is also working on a test for anemia.

**About Hemex Health**

Hemex Health develops and commercializes diagnostic technologies that help make affordable life-sustaining medical care possible for people everywhere. The company targets some of the world's most deadly diseases, including malaria, sickle cell disease, and COVID-19. The Gazelle technology was developed in collaboration with Case Western Reserve University. HemexDx, a subsidiary of Hemex Health, is located in Mumbai, India. More information can be found by going to [www.hemexhealth.com](http://www.hemexhealth.com).

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