# Hemex Health

Contact: David Sheon dsheon@whitecoatstrategies.com 202 422-6999

### **NEWS / FOR IMMEDIATE RELEASE**

## Researchers from India's National Institute of Research in Tribal Health Confirm Gazelle's Ability to Accurately Diagnose Sickle Cell Disease in Remote Regions

## Rapid, Low-Cost, Point-of Care Diagnostic Could Improve Patient Care and Save Lives in Hard to Test Areas

(Mumbai, India and Portland, Ore. – 13 October 2021) Research <u>published</u> today in the journal <u>Frontiers in Medicine</u> found that Gazelle<sup>™</sup>, a diagnostic platform from Hemex Health, has 99% accuracy in diagnosing sickle cell disease (SCD). The research team, from India's National Institute of Research in Tribal Health (NIRTH), have been hoping to find a low cost, highly accurate, point-of-care rapid detection test for SCD because current testing requires sending samples to a lab, resulting in delays, inability to communicate with patients, and in some cases corruption of the studies due to heat or rough conditions.

"At least 15% of all newborns with sickle cell disease are from India, and it is estimated that 20% of Indian children with sickle cell disease die from related illnesses before reaching their second birthday," as per ICMR study, said Dr. Shanmugam Rajasubramaniam, (Head, Division of Genetic Disorders, ICMR-National Institute of Research in Tribal Health). "Early diagnosis could start these children on life-saving therapies, but only a few public health facilities for diagnosis of sickle cell disease and patient care exist. A device like Gazelle that can be taken to remote areas could expand patient care significantly and save many lives."

In the study, the NIRTH team tested Gazelle to compare its accuracy against the standard laboratory tests, HPLC and hemoglobin electrophoresis. The results showed Gazelle performing with similar accuracy, but with more speed and ease.

The study included 960 subjects from the tribal states of Chhattisgarh and Madhya Pradesh, who ranged in age from 6 months to 65 years. Gazelle identified all patients with disease (HbSS) with 100% accuracy. Gazelle demonstrated 100% sensitivity when comparing sickle cell *disease* versus sickle cell *trait* and sickle cell disease versus normal. Gazelle exhibited high sensitivity and specificity for detection of each relevant hemoglobin phenotype (normal, carrier, and disease states). Overall, Gazelle yielded a high accuracy (99.0%) compared to the reference standard tests, hemoglobin electrophoresis and HPLC.

"Hemex recognizes the critical need for at-risk populations to have access to affordable, accurate testing," said Patti White, Co-founder and CEO, Hemex Health. "Clinicians in remote low resource locations told us what was needed, and we listened. Our sickle cell test uses a miniaturized version of electrophoresis – a technology widely known and trusted by clinicians – packaged in a portable, battery-powered device. We made it fast and easy-to-use with minimal training, and rugged enough for the hot and humid conditions that one often finds in the field."

Researchers noted many of Gazelle's ease-of-use features that would be valuable in field settings, including error detection software that senses problems with sample preparation and the automated interpretation of each sample. The short test time (about 12 minutes from sample to result) allows a report to be generated during the visit, ensuring that treatment and education can begin immediately. Because the device stores patient results locally or can transmit them to the cloud or printer, clinicians can easily track the patient's history.

#### About SCD

SCD is a hereditary condition affecting many tribal groups in India, and is also prevalent in Sub Saharan Africa, the Mediterranean region, and southeast Asia. SCD can result in severe morbidity and mortality if left unmanaged. Traditional screening methods (sample collection and transportation to a central lab) are not feasible for many rural populations.

#### **About Gazelle**

Gazelle is a compact, rugged, battery-operated diagnostic device. Gazelle can be used inexpensively, with no cold chain requirements by entry level healthcare workers in areas with limited access, resources, or electricity.

Patient information and results are captured digitally for storage, printing, or later transmission. Gazelle is approved for detecting malaria and sickle cell disease in a growing list of countries, and integrates miniaturized versions of trusted technologies, innovative optics, and artificial intelligence. This versatile approach allows the company to continually add diseases to its menu of tests and expand to new users. Gazelle is an accurate and rapid digital platform that can work about anywhere in the world.

With its affordable, compact, and rugged design, and all-day battery power, it delivers powerful, rapid diagnostics to more places without the need for a cold chain--from remote, low-resource settings, to drive through testing, border crossings, or nursing homes. Gazelle is approved for testing SCD in India, Ghana, Kenya, Tanzania, United Arab Emirates, Bahrain, and Kuwait and has CE mark. More information about Gazelle is available at https://hemexhealth.com/products.

**About Hemex** Health Hemex Health breaks traditional barriers with its innovative diagnostic system that expands the potential of diagnostics for emerging diseases, making accurate tests accessible to new locations and new populations. Hemex Health designs diagnostic technologies for the real world by listening to the needs of healthcare providers including those

in some of the most remote and challenging settings. The Gazelle technology was developed in collaboration with Case Western Reserve University. Hemex Health is located in Portland, Oregon, USA. HemexDx, a subsidiary of Hemex Health, is located in Mumbai, India. More information can be found by going to <u>www.hemexhealth.com</u>.

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