Hemex Health

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NEWS

For Immediate Release

New Research Confirms Hb Variant Test for Sickle Cell, Gazelle™, Useful for Screening and Tracking Treatment Management in Remote Settings, Advancing Doctors' Abilities to Better Detect and Manage the Disease

(June 20, 2024 – Portland, Ore., and Accra, Ghana) Hemex Health announced that the results of two investigations into the effectiveness of their Gazelle™ point-of-care Hb Variant test confirm that the test is suitable for screening for sickle cell disease in remote settings and is highly accurate for use in therapy monitoring.

The two studies, based in Ghana, demonstrate the value of the Gazelle™ Hb Variant test in multiple environments and use cases. The studies, one set in an urban hospital and the other in rural primary care clinics, show the utility and accuracy of Gazelle for sickle cell testing and use in therapy monitoring at point of care.

Researchers believe the findings are significant because populations with a high prevalence of the sickle cell gene living in remote settings often lack access to testing. The Gazelle test allows these patients to be tested near their homes, avoiding significant travel or the wait times involved with sending tests off to a central lab.

Data from the studies were presented recently at conferences.

Cathy Segbefia, MD, Department of Child Health, University of Ghana Medical School and Korle Bu Teaching Hospital, Accra, Ghana presented "Point-of-care diagnostic for foetal haemoglobin quantification in children undergoing hydroxyurea therapy for Sickle Cell Disease (SCD) in Ghana" at the 2024 Foundation for Sickle Cell Research conference in Ft. Lauderdale, Florida on June 9th.

The purpose of this study was to assess the use of Gazelle for monitoring patients on hydroxyurea. Hydroxyurea is a treatment that encourages production of fetal hemoglobin in patients with SCD, with the effect of mitigating many of the complications due to the disease. The study, led by Dr. Segbefia, shows that Gazelle could accurately quantify fetal hemoglobin levels in patients who used the drug and that Gazelle's correlation with HPLC (a high-end laboratory test) was 0.98.

"Gazelle is revolutionizing how we think about testing for sickle cell disease," said Dr. Segbefia. "Its ability to quantify the Hb variants is what gives it the edge among all available SCD point-of-care tests on the market. No longer do we have to rely on expensive and time-consuming lab-based tests to determine Hb F levels."

The second study, “Integration of point of care testing in primary health care facilities for early comprehensive management of sickle cell disease in rural Kassena Nankana Districts of Ghana,” which was led by Isaac Odame MD, Professor and Director of the Division of Adult and Paediatric Haematology, University of Toronto and Medical Director of the Global Sickle Cell Disease Network will be presented at a poster session at the European Hematology Association (eHA) Hybrid Congress on June 14 by team member Lucy Osei Ababio of the Navrongo Health Research Centre.

This study, located in a rural area of northern Ghana, focused on the feasibility of integrating Gazelle for SCD screening at primary health facilities with the aim of starting patients on early comprehensive care. The study showed that integrating Gazelle into existing primary healthcare programs, especially vaccination appointments, is not only feasible, but can be rapidly accomplished.

Sickle cell is a significant health issue in Ghana, and at least 2% of all newborns are affected by the disease.[i] However, access to testing and care facilities are limited, especially for families in rural areas.

“We are very excited by the results of these two studies because they demonstrate that Gazelle can be efficiently and affordably integrated into existing workflows at point of care to address unmet testing needs,” said Patti White, Hemex CEO. “These sites continue to use Gazelle because they see the advantage of having this information available quickly and locally for testing and treatment. We have every reason to believe that the success of Gazelle in one of the most demanding, difficult remote regions in Ghana will translate to better SCD management worldwide.”

About Sickle Cell Disease

According to research published in Lancet Haematology by the Institute for Health Metrics and Evaluation, despite being considered a “rare” disease, sickle cell affects a vast number of people throughout the world, with high concentrations in Africa, India, the Middle East, and some Mediterranean countries. In parts of West Africa, like Nigeria and Ghana, it can affect up to 2% of births. Nearly 8 million people were living with sickle cell disease in 2021. A person with sickle cell disease is also more likely to die from diseases that are common in these regions, such as diarrhea, pneumonia, and malaria. According to the IHME report, policy recommendations to improve sickle cell outcomes includes

- Improve screening systems for newborns, so parents are aware that their children are more vulnerable to common illnesses.
- Increase access to drugs like hydroxyurea that can treat sickle cell disease.
- Address elements of structural racism that have led to less funding and fewer options for treatment, compared to other similar genetic diseases.

About Gazelle

Gazelle is a compact, rugged, battery-operated *in vitro* diagnostic platform that uses artificial intelligence, innovative optics, and miniaturization to help a broader range of users to diagnose diseases in underserved areas.

It is used inexpensively 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 identifying sickle cell disease and beta thalassemia in over 35 countries. 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 in the most demanding environments in the world. More information about Gazelle is available at https://hemexhealth.com/products.

About Hemex

Hemex Health impacts health outcomes in the world's most challenging markets by developing affordable point-of-care diagnostics that quickly deliver reliable results.

The company's diagnostic solutions are affordable for both low- and high-income areas, simple enough to be used by anyone, and designed to provide reliable answers for clinicians to immediately take action.

Hemex is driven to democratize diagnostics for patients with the greatest needs.

The Gazelle technology was developed in collaboration with Case Western Reserve University. Hemex Health is in Portland, Oregon, U.S.A and Mumbai, India. More information can be found at www.hemexhealth.com.

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[i] Kyerewaa Edwin A, Edwin F, Etwire V. Controlling Sickle Cell Disease in Ghana--ethics and options. Pan Afr Med J. 2011;10:14. doi: 10.4314/pamj.v10i0.72223. Epub 2011 Oct 3. PMID: 22187596; PMCID: PMC3282939.