

Hemex Health Awarded \$3M NIH Grant to Bring Gazelle Hb Variant Test for Sickle Cell Disease to US Market

Portland-Based Company Seeks to Bring Affordable Sickle Cell and Beta Thalassemia Test to the US – Currently Used in 27 Countries

Portland, Ore. – March 27, 2023 – [Hemex Health](#), a medical diagnostic device company focused on expanding healthcare access to underrepresented patient populations, announced it has been awarded a 3-year, \$3 million grant from the National Heart, Lung, and Blood Institute (NHLBI). NHLBI, part of the National Institutes of Health, awarded a SBIR Phase IIB Bridge Award to Hemex to advance the commercialization of the company's Gazelle® Hb Variant Test for the United States market.

Hemex intends to use the grant to complete activities required for FDA 510(k) clearance.

The Hb Variant Test, one of the tests supported by the Gazelle diagnostic platform, can detect Sickle Cell Disease (SCD) and beta thalassemia – genetic blood disorders that can result in debilitating pain, disability, severe complications or death.

As an affordable, portable, point-of-care test, Gazelle's results are equivalent to standard lab tests but do not require complex logistical support. Gazelle is highly accurate: [previous research](#) found that it can detect SCD with 99% accuracy. The device and cartridges are designed to be affordable for underrepresented communities, and test results appear onscreen in only eight minutes.

"An accurate point-of-care test for sickle cell disease and trait is crucial in helping address the challenges of misdiagnosis and undiagnosed patients who could potentially miss out on life saving medical care," said Dr. Stephen Boateng, Director of Research, [Sickle Cell 101](#), a non-profit patient group providing sickle cell education to individuals impacted by the condition in the U.S. and globally. "Such a test that can also provide results in minutes provides an additional benefit, especially during community outreach events where participants could be lost to follow up due to the length of time it might take for results to come back."

Armed with these advantages, Gazelle is helping to revolutionize the diagnosis of these disorders, having conducted hundreds of thousands of tests in 27 countries across India, Africa, the Middle East, and Southeast Asia. Gazelle is bringing highly accurate testing to low resource populations who have never had access to this level of testing.

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With this grant, Hemex seeks to replicate its international success and expand into the United States.

The [CDC](#) states that genetic blood disorders are most prevalent among Americans of African, Hispanic, Indian, Mediterranean, and Southeast Asian descent. The [American Society of Hematology \(ASH\)](#) estimates that 100,000 Americans have SCD and that up to three million are carriers, including up to 8% of African-Americans. In the US, the [CDC](#) says that SCD can decrease life expectancy by up to 20 years.

“Millions of Americans are carriers of the sickle cell trait or beta thalassemia trait, but according to research, only a small percentage know their status,” said Patti White, CEO, Hemex Health. “This test can empower people to quickly learn their status, which may impact family planning or other important decisions.”

“As we have done around the world, Hemex hopes to use our products to bring the needs of sickle cell and beta thalassemia patients into the light of day by reaching the hard-to-reach, and providing this population with the diagnoses they need to get effective treatment,” said Ms. White. “I am incredibly proud of our team and our products, and grateful to NHLBI for the opportunity they have given us to bring our work to the US.”

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About Gazelle

Gazelle is a compact, rugged, battery-operated *in vitro* diagnostic device. It is 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 sickle cell disease and beta thalassemia 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 – from remote, low resource settings to drive-through testing, border crossings, or nursing homes. More information about Gazelle is available at <https://hemexhealth.com/products>.

About Hemex

Hemex Health breaks traditional barriers with its innovative diagnostic system that expands the potential of diagnostics for important conditions, 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 in Portland, Oregon, U.S.A. More information can be found at www.hemexhealth.com.

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