Hemex Health

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FOR IMMEDIATE RELEASE

Hemex Health Receives FDA Breakthrough Device Designation for Gazelle® Hb Variant Test

Designation Recognizes Potential to Address Unmet Needs in Sickle Cell Disease Monitoring

PORTLAND, Ore. — [February 6, 2026] — Hemex Health, a medical diagnostics company focused on decentralized testing for blood-based conditions, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to its Gazelle® Hb Variant Test.

The FDA's Breakthrough Devices Program is intended to expedite the development, assessment, and review of medical devices that have the potential to provide more effective diagnosis or treatment of life-threatening or irreversibly debilitating diseases. Through the program, Hemex will receive prioritized interaction and feedback from the FDA as it advances development of the Gazelle Hb Variant Test.

"The Breakthrough Device Designation reflects the FDA's recognition of the need for improved tools to support the management of sickle cell disease," said Patti White, CEO of Hemex Health. "We appreciate the opportunity for early and frequent engagement with the agency as we continue to develop diagnostic technologies intended to deliver clinically meaningful information closer to patients."

The Gazelle® platform is designed to rapidly separate and detect hemoglobin fractions and variants using miniaturized electrophoresis technology, with the goal of enabling decentralized access to quantitative hemoglobin data. Hemex is exploring the potential role of this technology in supporting therapeutic monitoring and disease management in sickle cell disease and other hemoglobinopathies.

Hemex recently presented multiple scientific posters and an oral presentation related to sickle cell disease diagnostics and monitoring at the 66th American Society of Hematology (ASH) Annual Meeting, reflecting ongoing research and clinical engagement around hemoglobin variant testing.

The Gazelle Hb Variant Test has not been cleared or approved by the FDA and is not available for sale in the United States. Breakthrough Device Designation does not guarantee regulatory clearance.

About Hemex Health

Hemex Health impacts health outcomes in the world's most challenging markets by developing affordable point-of-care diagnostics that quickly deliver clinically actionable diagnostic solutions for blood-based conditions. The company's diagnostic solutions are affordable for both low- and high-income areas and simple enough to be used by anyone.

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