

Devyser launches the first IVDR compliant NGS assay for thalassemia and sickle cell disease testing

Devyser, today announced the launch of *Devyser Thalassemia v2*, the first Next-Generation Sequencing (NGS) assay for genetic analysis of thalassemia and sickle cell disease (SCD) available on the European market under the In Vitro Diagnostic Regulation (IVDR).

Thalassemia and SCD are among the most common inherited blood disorders globally, caused by mutations in the HBA1, HBA2, and HBB genes. Comprehensive and accurate genetic analysis is essential for diagnosis, carrier screening, and informed clinical decision-making. Devyser Thalassemia v2 leverages advanced NGS technology to enable high-resolution detection of clinically relevant variants, providing laboratories with a streamlined, reliable, and regulatory-compliant solution.

Developed in accordance with IVDR requirements, the assay offers robust analytical performance, broad variant coverage, and an efficient laboratory workflow, helping consolidate testing into a single comprehensive assay while meeting the highest quality and regulatory standards. Devyser Thalassemia v2 is designed to support clinical laboratories across Europe in delivering precise and timely results.

“The launch of Devyser Thalassemia v2 represents a major milestone for Devyser and genetic diagnostics in Europe,” said Jan Wahlström, CEO, Devyser. “Being first to market with an IVDR-compliant NGS assay for thalassemia underscores our commitment to innovation, regulatory excellence, and enabling laboratories to provide high-quality diagnostics that truly impact patient care.”

“Thalassemia testing requires both precision and reliability, particularly in regions with high carrier frequency,” said Theis Kipling, CCO, Devyser. “With this launch, we are equipping laboratories with a future-proof solution that not only meets IVDR requirements but also strengthens their ability to deliver accurate results with confidence and efficiency.”

The introduction of Devyser Thalassemia IVDR further expands the company’s growing portfolio of IVDR-compliant solutions, reinforcing Devyser’s position as a trusted partner to clinical laboratories worldwide.

For more information, please contact:

Jan Wahlström, CEO

E-mail: ir@devyser.com

Telephone: +46 8 562 158 50

Theis Kipling, CCO

E-mail: ir@devyser.com

Telephone: +46 8 562 158 50



PRESS RELEASE
04 March 2026 10:00:00 CET

About Devyser

Devyser is redefining how laboratories approach genetic testing. As your true one-stop shop, we offer streamlined solutions for a wide range of conditions, helping labs overcome complexity, reduce turnaround times, and maximize efficiency.

Our technologies simplify workflows, minimize hands-on time, and deliver fast, accurate results. Every test is designed to empower labs to do more with less, freeing up resources while supporting better patient outcomes.

We specialize in diagnostic kits and advanced analysis services for clinical genetics and post-transplantation laboratories - two critical areas where accuracy and speed matter. With customers in 65+ countries, we also operate our own CLIA-certified laboratory, Devyser Genomic Laboratories, in Atlanta and maintain sales offices across Europe and the US.

Devyser is committed to regulatory excellence under IVDR, ensuring the highest quality standards across our growing product portfolio.

Founded in 2004 and headquartered in Stockholm, Devyser is listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). Redeye Sweden AB is the company's Certified Adviser.

Discover how we're shaping the future of lab diagnostics at www.devyser.com.