PRESS RELEASE
28 November 2025 15:00:00 CET

Devyser strengthens U.S. market presence with CMS pricing for PrenatalDetect RHD test

Devyser today announced that the Centers for Medicare & Medicaid Services (CMS) has issued its final pricing determination for the company's PrenatalDetect RHD test (CPT 0536U) at $192. The non-invasive fetal RhD genotyping test is performed at Devyser Genomic Laboratories, the company's CLIA-certified and CAP-accredited facility in the United States. The pricing will be reflected in the 2026 Medicare Clinical Laboratory Fee Schedule (CLFS) and will take effect on January 1, 2026.

"This achievement marks an important milestone for Devyser Genomic Laboratories. The CMS pricing determination facilitates reimbursement for our PrenatalDetect RHD test and supports our mission to provide innovative, high-quality prenatal diagnostics to expectant mothers" said Jan Wahlström, CEO, Devyser.

Medicare pricing often serves as a benchmark for private insurer reimbursement, paving the way for broader coverage and improved access. This decision also aligns with the 2024 clinical guidelines issued by the American College of Obstetricians and Gynecologists (ACOG), which recommend wider use of fetal RhD genotyping to optimize the limited supply of anti-D immunoglobulin.

"By establishing a competitive price for our PrenatalDetect RHD test, CMS has made this technology more accessible to patients, providers, and payors alike. This will help enable equitable access to high-quality prenatal testing across the healthcare system," said Theis Kipling, CCO, Devyser.

About PrenatalDetect RHD
PrenatalDetect RHD service offers a highly sensitive and accurate test for non-invasive fetal RHD screening. By determining fetal RHD status from maternal plasma, it provides information on fetal RHD status that may support clinical decision making in Rh-negative pregnant women and help streamline patient testing workflows.

Disclaimer: PrenatalDetect RHD is a laboratory-developed test offered exclusively by Devyser Genomic Laboratories. It was developed and validated under CLIA for high-complexity testing. This test has not been cleared or approved by the FDA. Results should be interpreted with other clinical and laboratory findings.

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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). The company´s Certified Adviser is Redeye AB.

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

This information is information that Devyser Diagnostics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-11-28 15:00 CET.