

## Health Canada grants IVD approval to Devyser's NGS-based chimerism test, the first of its kind in Canada

Devyser is proud to announce that **One Lambda Devyser Chimerism** and **Advyser Chimerism** have been granted approval as **Class III In Vitro Diagnostic (IVD)** medical devices by Health Canada. With this we set a new standard for post-transplant monitoring nationwide as this is the first ever IVD-marked chimerism test to receive approval in Canada.

The approval underscores Devyser's dedication to providing laboratories and clinicians with high-precision, user-friendly solutions for post-transplant monitoring. **One Lambda Devyser Chimerism** enables highly accurate quantification of donor and recipient DNA following hematopoietic stem cell transplantation (HSCT) allowing clinicians to detect graft rejection or disease relapse at an early stage. **Advyser Chimerism** is our data analysis software that complements the assay by streamlining interpretation, reporting, and data management.

"Achieving Class III IVD approval in Canada and being the first chimerism assay to do so, is a true reflection of teamwork," said Jan Wahlström, CEO, Devyser. "This also reflects Devyser's commitment to supporting laboratories, clinicians, and patients through reliable, high-quality molecular diagnostic solutions."

With this approval, Canadian laboratories can now implement Devyser's complete chimerism workflow, benefiting from a simplified process, rapid turnaround, and enhanced confidence in post-transplant monitoring.

*One Lambda Devyser Chimerism and Advyser Chimerism are currently available under an exclusive collaboration and distribution agreement between Devyser and Thermo Fisher Scientific.*

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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](https://www.devyser.com).