

Devyser signs in vitro diagnostic agreement with Illumina to broaden access to its tests

Devyser Diagnostics AB has entered an in vitro diagnostic development agreement with Illumina, Inc. (Nasdaq: ILMN). The agreement enables Devyser to develop and offer its in vitro diagnostic (IVD) tests on Illumina MiSeqDx next-generation sequencing (NGS) instrument in the United States and Europe.

The IVD development agreement allows Devyser to perform regulatory registrations of its tests on Illumina MiSeqDx sequencing instrument. The agreement confirms Illumina's commitment to support Devyser in its registrations and enables Devyser to develop end-to-end IVD approved NGS testing solutions on the FDA regulated and CE-IVD–marked MiSeqDx sequencing platform.

"With this agreement, we are taking an important step towards giving more laboratories access to Devyser's simple, fast, and effective genetic testing solutions, and to provide patients with the best possible care." says Fredrik Alpsten, Devyser CEO. "Illumina are a natural partner to us, with their market-leading position and ever-growing base of installed NGS IVD instruments."

"We are very pleased to partner with Devyser to enable the development of end-to-end, clinical NGS testing solutions," says Joydeep Goswami, Chief Strategy and Corporate Development Officer and Chief Financial Officer of Illumina. "We believe that together we will help to broaden market access to NGS solutions that enable patients and physicians to make better informed and timely decisions."

Illumina MiSeqDx System is the first FDA–regulated, CE-IVD–marked, NGS platform for IVD testing. With regulatory approvals in over 50 countries, MiSeqDx has become a trusted platform for hospitals and clinical laboratories running a menu of high-quality diagnostic tests.

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About Devyser

Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 50 countries. Our products are used for advanced genetic testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up. Devyser's products, and unique, patented solution requiring only one test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of our business and an important prerequisite for long term value creation.

Devyser was founded in 2004 and is based in Stockholm, Sweden with eight in-house sales offices in Europe and the US. The company also runs Devyser Genomic Laboratories, a CLIA certified laboratory in Atlanta, US. In 2022, Devyser's quality management system was certified according to the IVDR and a number of the company's products have since been certified according to the IVDR.

Devyser's shares are listed on the Nasdaq First North Premier Growth Market Stockholm (ticker: DVYSR). The company's Certified Adviser is Redeye AB.

For more information, visit www.devyser.com.