

Devyser achieves breakthrough in the US with cystic fibrosis NGS test

Devyser has secured a CFTR NGS proposal with UNC Hospitals. The proposal with UNC Hospitals is valid for a period of up to four years. Indicative order value is estimated to be approximately 2.5 million SEK annually.

"Devyser CFTR NGS is one of the few products that meet the newly implemented ACMG recommendations. This is the first deal secured for Devyser CFTR NGS in the US, and I am very proud of the entire team who made this happen. We are also very optimistic for the future of Devyser CFTR NGS, especially in the US, where we see a lot of interest," said CEO Fredrik Alpsten. "This proposal is another confirmation of the competitiveness of our high quality and simple CFTR NGS solution."

In 2023, ACMG (the American College of Medical Genetics and Genomics) updated its recommendations regarding the number of screening variants, from 23 to 100. Devyser CFTR NGS captures all cystic fibrosis gene (*CFTR*) mutations, including the 100 from the ACMG recommendations, in a single assay that is designed for fast and efficient lab processing.

Cystic fibrosis is a progressive, genetic disease that affects the lungs, pancreas, and other organs. Approximately 1.4 million cystic fibrosis genetic tests are performed each year in the US [1].

Devyser CFTR NGS is for Research Use Only (USA and Canada). Not for use in diagnostic procedures.

[1] Lyon E, Schrijver I, Weck KE, Ferreira-Gonzalez A, Richards CS, Palomaki GE; CAP/ACMG Biochemical and Molecular Genetics Committee. Molecular genetic testing for cystic fibrosis: laboratory performance on the College of American Pathologists external proficiency surveys. Genet Med. 2015 Mar;17(3):219-25. doi: 10.1038/gim.2014.93. Epub 2014 Jul 31. PMID: 25077647.

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About Devyser

Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 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.