Press Release
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Qlucore Launches First CE-Marked Diagnostic Test for Pediatric Leukemia

Qlucore introduces the first CE-marked diagnostic test for pediatric leukemia according to the mandatory regulatory framework in Europe (IVDR). Now available for delivery and clinical use, Qlucore Diagnostics provides enhanced accuracy and marks a significant step forward in the ability to diagnose this common childhood cancer. With improved diagnosis, more personalized treatment and better outcomes become possible.

Qlucore Diagnostics BCP-ALL is the first CE-marked (IVDR) diagnostic test designed to improve the diagnosis and treatment of pediatric acute leukemia. The test is delivered as a software solution and uses AI-based machine learning. The test was developed in collaboration with Dr. Thoas Fioretos, Professor of Clinical Genetics, and his team at Lund University in Sweden.

Sales of Qlucore Diagnostics 1.0 for BCP-ALL start as of now in Europe. Future tests for lung cancer, acute myeloid leukemia, and bladder cancer are in development.

B-cell precursor acute lymphoblastic leukemia (BCP-ALL), the most common childhood cancer, is characterized by genetic alterations of importance for diagnostics and treatment. Qlucore Diagnostics BCP-ALL is designed to qualitatively analyze genetic alterations associated with BCP-ALL following a method called RNA-sequencing. The software analyses gene expression levels by employing a machine learning-based (AI) model to classify the patient into the six most common subtypes of BCP-ALL. This classification can then aid in the accurate sub-grouping and management of children diagnosed with BCP-ALL. The software also displays and ranks gene fusions, which are crucial in the diagnostics workup as they can drive disease development as well as response to treatment. Thus, identifying these fusions supports critical treatment decisions.*

"The launch of Qlucore Diagnostics for pediatric leukemia underscores our commitment to advancing precision medicine and improving patient outcomes. As the only IVDR-approved software available in this space, we are proud to provide clinical laboratories with a unique, user-friendly test that enhances diagnostic accuracy and efficiency. This test is the first in a suite of products built on our innovative platform, marking a significant step forward in data-driven diagnostics." says Carl-Johan Ivarsson, CEO of Qlucore.

"The introduction of the Qlucore Diagnostics BCP-ALL diagnostic software solution represents a significant step forward in personalized medicine for children diagnosed

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with acute lymphoblastic leukemia. By integrating advanced genetic analysis with user-friendly software, it is now possible to provide diagnostic laboratories and clinicians with a faster and more accurate diagnosis, ultimately improving outcomes for these children. It's been an incredible journey to see this collaboration come to life, and I'm proud of the impact it will have on the future care of children diagnosed with BCP-ALL.", added Dr. Thoas Fioretos, Professor of Clinical Genetics, Lund University.

The CE mark, granted by the British Standards Institution (BSI), confirms that the Qlucore Diagnostic BCP-ALL test meets the rigorous health, safety, and performance standards required for in vitro diagnostics in the European Economic Area (EEA). This certification enables the test to be marketed and used across Europe, ensuring broader access for clinicians and healthcare providers. By meeting these stringent regulatory requirements, the CE mark reinforces confidence in the test's reliability, safety, and clinical utility, supporting its adoption as a valuable tool in the diagnosis and treatment of BCP-ALL.

*This is a simplified description of the intended use, visit qlucore.com for full details.

Certified Advisor

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About Qlucore

Qlucore is a leading provider of new generation intuitive bioinformatics software for research and precision and companion diagnostics. Qlucore's mission is to make it easier to analyze the huge amounts of complex data generated by innovations in the fields of genomics and proteomics by providing powerful visualization-based bioinformatics data analysis tools for research and precision diagnostics. Qlucore Omics Explorer software is a easy to use bioinformatics software for research in the life science, plant- and biotech industries, as well as in academia. Qlucore Diagnostics and Qlucore Insights are software platforms with built in AI-based machine learning for multi-omics companion and precision diagnostics. Qlucore was founded in 2007 in Lund, Sweden and has customers in about 25 countries around the world, with sales offices in Europe and North America, and distribution in several countries in Asia. Qlucore is listed on the Nasdaq First North Growth market. **www.qlucore.com**

Attachments

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