Labcorp Achieves IVDR CE-Marking for PGDx elio™ tissue complete in the EU

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First-and-only test of its kind approved under new European Union regulations expands access to personalized cancer care for patients across the EU

BURLINGTON, N.C., July 29, 2025 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today PGDx elio™ tissue complete has been CE-marked under the European Union's (EU) new In Vitro Diagnostic Regulation (IVDR). It is now the first and only test of its kind in the EU CE-marked for comprehensive solid tumor profiling. This marks a significant milestone in expanding access to personalized treatment options for the approximately 2.7 million people diagnosed with cancer every year in the EU.

This in vitro diagnostic (IVD) assay, which has been cleared by the U.S. Food and Drug Administration (FDA), supports physicians in delivering guideline-based care for patients with solid tumors. Its ability to simultaneously analyze multiple biomarkers, even with limited tissue samples, enables insights that can support patient care and clinical management. For many, this could mean the difference between starting an effective patient management plan sooner or facing delays that could impact their prognosis. With this CE-marking, the test can now be offered by more laboratories across the EU, expanding patient access to personalized cancer care.

"This accomplishment reflects Labcorp's commitment to advancing precision medicine and improving patient care," said Shakti Ramkissoon, M.D., Ph.D., MBA, vice president, medical lead for oncology at Labcorp. "With both FDA clearance and IVDR CE-mark, this test sets a new standard for quality and performance in cancer diagnostics. Importantly, it also provides our biopharma partners with a reliable, regulatory-ready solution to de-risk multiyear clinical trial strategies, ensuring continuity in NGS testing for trials that will extend beyond the IVDR transition timelines."

PGDx elio tissue complete makes it easier for laboratories to bring testing in-house while lowering costs, accelerating implementation, and helping patients get tested sooner.

As Labcorp prepares to make the CE-marked assay available for biopharma partners and for investigational use in global clinical trials through Labcorp's central laboratory in Geneva, Switzerland, the company remains focused on its core mission: improving health and improving lives. This latest achievement is a testament to that commitment, paving the way for more personalized and accessible cancer care for patients across Europe and beyond.

For more information, visit https://www.labcorp.com/ivdr-elio-tissue-complete.

About Labcorp
Labcorp (NYSE: LH) is a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. We provide insights and advance science to improve health and improve lives through our unparalleled diagnostics and drug development laboratory capabilities. The company's nearly 70,000 employees serve clients in approximately 100 countries, provided support for more than 75% of the new drugs and therapeutic products approved in 2024 by the FDA, and perform more than 700 million tests annually for patients around the world. Learn more about us at www.labcorp.com.

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