



## Labcorp Receives FDA De Novo Marketing Authorization for PGDx elio™ plasma focus Dx

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*PGDx elio™ plasma focus Dx is the industry's first and only kitted, pan-solid tumor liquid biopsy test that enables tumor mutation profiling – all from a simple blood draw*

BURLINGTON, N.C., Aug. 2, 2024 /PRNewswire/ -- [Labcorp](#) (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today it has received De Novo marketing authorization from the U.S. Food and Drug Administration (FDA) for [PGDx elio™ plasma focus Dx](#) – the industry's first and only kitted, pan-solid tumor liquid biopsy test.



PGDx elio plasma focus Dx builds on the success of [PGDx elio™ tissue complete](#) and enables laboratories to perform genomic profiling when tissue is limited or unavailable.

"The launch of PGDx elio plasma focus Dx represents a landmark expansion of Labcorp's suite of precision oncology solutions," said Shakti Ramkissoon, M.D., Ph.D., MBA, vice president, medical lead for oncology at Labcorp. "This latest liquid biopsy test offers laboratories and oncologists a convenient, cost-effective and highly targeted tumor-profiling solution that spans a wide range of solid-tumor types – particularly when tumor tissue is limited or unavailable. When paired with PGDx elio tissue complete, Labcorp now offers laboratories access to tissue and liquid genomic-profiling assays that operate on the same instrument, enabling seamless integration of these precision oncology products into routine laboratory workflows. The ability to test tissue or liquid will provide critical data and insights needed to inform more personalized treatments and care plans for patients."

PGDx elio plasma focus Dx is a qualitative next-generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for the detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 33 genes, copy number amplifications (CNAs) in five genes, and translocations in three genes. The assay targets guideline-recommended biomarkers to enable more accurate clinical assessments and is coupled with automated bioinformatics to deliver accelerated results. This solution enhances oncologists' ability to make timely treatment decisions in conjunction with other laboratory and clinical findings while also promoting sample and data ownership.

PGDx elio plasma focus Dx is part of Labcorp's comprehensive precision [oncology portfolio](#) of testing solutions. For more information, visit <https://www.personalgenome.com>

### 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 more than 67,000 employees serve clients in approximately 100 countries, provided support for 84% of the new drugs and therapeutic products approved in 2023 by the FDA and performed more than 600 million tests for patients around the world. Learn more about us at [www.labcorp.com](http://www.labcorp.com).

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