Labcorp Announces FDA Approval of Companion Diagnostic Supporting Patients with Advanced Melanoma

August 10, 2026

- *Labcorp's FDA-approved PGDx elio® tissue complete CDx helps identify advanced melanoma patients with certain BRAF variants eligible for BRAF and BRAF/MEK inhibitor therapies*
- *Supports access to targeted treatment options for the deadliest form of skin cancer*

BURLINGTON, N.C., Aug. 10, 2026 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, today announced that the U.S. Food and Drug Administration (FDA) has approved Labcorp's PGDx elio® tissue complete CDx as a companion diagnostic to help identify patients with advanced melanoma with certain BRAF variants who may benefit from treatment with FDA-approved targeted therapies[i].

Addressing a Critical Need in Advanced Melanoma
Melanoma is the deadliest form of skin cancer, with a five-year survival rate of just 16% for patients diagnosed with stage IV disease. However, targeted therapies are an important treatment option for patients with advanced melanoma whose tumors have a BRAF alteration. As a companion diagnostic, PGDx elio tissue complete CDx helps clinicians identify which melanoma patients carry these BRAF V600E/K variants and may benefit from treatment with FDA-approved BRAF inhibitors and BRAF/MEK inhibitor combination regimens.

"Advanced melanoma is an extremely aggressive and life-threatening cancer, but targeted treatments are offering real hope for patients," said Shakti Ramkissoon, M.D., Ph.D., vice president, medical lead for oncology at Labcorp. "Labcorp's FDA-approved companion diagnostic improves access to these therapies by allowing clinicians to confirm which patients may be eligible for and can start receiving those treatments as soon as possible."

A Comprehensive and Scalable Testing Solution
Labcorp's PGDx elio tissue complete CDx is approved for use by qualified healthcare professionals across hospitals and clinical laboratories, supporting broader patient access to high-quality molecular testing. As a kit-based solution, the companion diagnostic can be implemented directly within hospitals and health systems, expanding access to testing while enabling organizations to retain samples and data that may inform future clinical research.

The addition of Labcorp's PGDx elio tissue complete CDx reflects the continued expansion of Labcorp's precision medicine portfolio, which includes comprehensive tissue- and liquid-based oncology diagnostics designed to support personalized care. For more information about PGDx elio tissue complete or Labcorp's oncology solutions, visit https://www.labcorp.com/oncology/providers/testing-solutions/kitted-solutions/pgdx-elio-tissue-complete-cdx.

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 71,000 employees serve clients in approximately 100 countries, provided support for more than 85% of the new drugs and therapeutic products approved by the FDA in 2025 and performed more than 750 million tests for patients around the world. Learn more at www.labcorp.com.

[i]PGDx elio tissue complete CDx is a qualitative next generation sequencing-based in vitro diagnostic device that uses a high-throughput hybridization-based capture technology utilizing DNA isolated from formalin-fixed paraffin embedded tumor tissue. The PGDx elio tissue complete CDx targeted panel can detect single nucleotide variants, small insertions and deletions, copy number amplifications, and translocations. It is intended to be used as a companion diagnostic to identify melanoma patients who may benefit from treatment with targeted therapies listed below in accordance with the approved therapeutic product labeling.

PGDx elio tissue complete CDx Indications
Indication: Melanoma
Biomarker: BRAF V600E/ BRAF V600K
Therapy: BRAF inhibitors approved by FDA or BRAF/MEK inhibitor combinations approved by FDA

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