Labcorp Launches Molecular Residual Disease and Liquid Biopsy Solutions

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Labcorp® Plasma Detect™ now available for clinical use to assess risk of recurrence in stage III colon cancer patients

FDA-authorized liquid biopsy assay PGDx elio® plasma focus™ Dx now available to support treatment selection

BURLINGTON, N.C., April 23, 2025 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today the expansion of its precision oncology portfolio with two solutions: Labcorp Plasma Detect for clinical use to help assess the risk of disease recurrence in stage III colon cancer patients, and the availability of PGDx elio plasma focus Dx, the first and only kitted, pan-solid tumor liquid biopsy test authorized by the U.S. Food and Drug Administration (FDA) to identify patients who may benefit from targeted treatments.

"Labcorp is dedicated to providing oncologists with a comprehensive portfolio of innovative solutions that enable precise, timely and personalized treatment decisions," said Shakti Ramkissoon, M.D., Ph.D., vice president, medical lead for oncology at Labcorp. "With the expansion of our portfolio to include Labcorp Plasma Detect for clinical use and the availability of PGDx elio plasma focus Dx to support patient treatment selection, we're advancing care across the oncology spectrum, solidifying our commitment to transforming cancer diagnostics and improving patient outcomes."

Labcorp Plasma Detect: Advanced Risk Assessment for Colon Cancer Patients
Stage III colon cancer has a nearly 30% recurrence rate within five years. Labcorp Plasma Detect is a blood-based test using whole-genome sequencing (WGS) to detect circulating tumor DNA (ctDNA), indicating the presence of molecular residual disease (MRD).[i] Patients who are MRD-positive after cancer treatment have a higher risk of recurrence and a poorer prognosis. Labcorp's test detects cancer recurrence risk that conventional methods might miss, helping to identify patients who could benefit from additional treatment or therapy.

Key Features of Labcorp Plasma Detect:

- The test is Labcorp's first tumor-informed MRD solution for clinical use to support recurrence risk stratification. Labcorp Plasma Detect launched in 2024 for biopharma use to support exploratory and investigational studies.
- The test combines a WGS approach, without the need for a bespoke panel, with proprietary bioinformatics to deliver ctDNA detection down to a limit of detection (LOD95) of 0.005%.
- Results are available approximately 14 days after Labcorp receives the initial sample, and seven days for subsequent monitoring time points for each patient.
- Labcorp Plasma Detect is currently being evaluated in more than 10 clinical studies in the U.S. and internationally to assess MRD across various cancer types.

Labcorp Plasma Detect will be offered initially through an Early Experience Program, with the intent to expand availability more broadly.

PGDx elio plasma focus Dx Now Available for Use to Aid in Treatment Selection

PGDx elio plasma focus Dx is the first and only kitted pan-solid tumor liquid biopsy test to receive De Novo authorization from the FDA. This assay provides oncologists with a validated tool to assess various solid tumors for targeted treatment selection – all from a simple blood draw.

Key Features of PGDx elio plasma focus Dx:

- The kitted model allows clinical laboratories and hospitals to retain control over patient specimens and data for research, care management and other clinical purposes.
- As an FDA-authorized assay, PGDx elio plasma focus Dx requires only on-site verification – as opposed to a full validation – enabling more rapid implementation.
- Once implemented, this rapid, scalable liquid biopsy genomic test provides actionable findings within a 4-to-5-day turnaround time, from isolated nucleic acid to variant report.
- As part of the PGDx elio platform, the kitted model is compatible with FDA-cleared PGDx elio™ tissue complete, enabling seamless, in-house tissue-to-liquid reflexing and efficient comprehensive genomic profiling workflows.

Labcorp at the American Association for Cancer Research (AACR) 2025 Annual Meeting
Labcorp will present key studies at the AACR 2025 Annual Meeting, including the clinical use of Labcorp Plasma Detect and performance of PGDx elio plasma focus Dx.

To learn more, or to connect with Labcorp at AACR in Chicago, visit https://oncology.labcorp.com/american-association-cancer-research-annual-meeting-2025

For more information about Labcorp's Oncology solutions, contact us at https://oncology.labcorp.com/contact-us

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.

[i] The term MRD is often used interchangeably between molecular residual disease and minimal residual disease. Labcorp Plasma Detect detects molecular residual disease, which is defined as the subclinical presence of a cancer-associated biomarker indicating a high risk of recurrence, which cannot be detected by standard imaging techniques. MRD terminology is in accordance with the BLOODPAC Consortium.

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