Labcorp Launches FDA-Approved PTEN Companion Diagnostic for Prostate Cancer

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First FDA-approved IHC assay identifies patients who may be eligible for combination treatment with TRUQAP® (capivasertib)

BURLINGTON, N.C., Aug. 4, 2026 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced the nationwide availability of Roche's VENTANA® PTEN (SP218) RxDx Assay, the first immunohistochemistry (IHC) companion diagnostic test approved by the U.S. Food and Drug Administration (FDA) to determine PTEN protein loss, also known as PTEN deficiency, in tumors of patients with prostate adenocarcinoma. The assay helps identify patients who may be eligible for treatment with AstraZeneca's TRUQAP® (capivasertib) in combination with abiraterone acetate and prednisone.

Addressing an Unmet Need in Prostate Cancer Care
Excluding skin cancer, prostate cancer is the most common cancer among men in the United States, with more than 330,000 new cases expected each year. PTEN is a tumor suppressor protein that plays a critical role in regulating cell growth. Loss of PTEN protein expression has been associated with more aggressive disease progression and reduced benefit from current standard-of-care therapies in prostate cancer. Until recently, there were no approved treatment options specifically targeting this biology.

The VENTANA PTEN (SP218) RxDx Assay is a companion diagnostic designed to detect PTEN protein loss in prostate cancer tissue specimens, providing clinicians with important biomarker information to help guide treatment decisions and support personalized patient care.

"Biomarker testing is essential to advancing precision oncology and helping connect patients with the therapies most appropriate for their disease," said Shakti Ramkissoon, M.D., Ph.D., vice president, medical lead for oncology at Labcorp. "The launch of the VENTANA PTEN (SP218) RxDx Assay underscores how Labcorp is expanding access to innovative companion diagnostics and delivering the timely insights physicians need to make personalized treatment decisions."

Advancing Access to FDA-Approved Companion Diagnostics
Labcorp participated in Roche's early access program to support Day 1 laboratory readiness for the assay, reinforcing the company's commitment to helping patients gain timely access to newly approved targeted therapies and the companion diagnostics needed to identify eligible patients.

The VENTANA PTEN (SP218) RxDx Assay is now available through Labcorp's national network of laboratories and complements the company's comprehensive portfolio of genomic, molecular and companion diagnostic testing services that support precision oncology care. As one of the nation's largest providers of oncology testing services, Labcorp enables physicians across community and academic settings to access FDA-approved companion diagnostics at scale, helping bring precision medicine to more patients regardless of where they receive care. The assay can also be ordered alongside Labcorp's broader portfolio of oncology testing services, providing clinicians with comprehensive biomarker insights from a single laboratory partner.

To learn more about the assay, visit https://oncology.labcorp.com/tests/484680/PTEN-IHC-with-interpretation-for-prostate-adenocarcinoma

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.

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