Labcorp to Offer First FDA-Cleared Blood Test to Rule out Alzheimer's-Related Amyloid Pathology in Primary Care Settings

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Labcorp plans to make Roche's Elecsys® pTau181 test available nationwide by early 2026

BURLINGTON, N.C., Oct. 23, 2025 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today it will offer the Elecsys pTau181 test, the only blood test cleared by the U.S. Food and Drug Administration (FDA) to aid in the initial assessment for Alzheimer's disease and other causes of cognitive decline in the primary-care setting. Developed by Roche Diagnostics, Labcorp plans to make the test available nationwide by early 2026.

An estimated 7.2 million Americans are living with Alzheimer's disease, a number expected to nearly double by 2050. Cognitive changes are often first identified during routine care visits, but Alzheimer's biomarker testing has traditionally required a specialist referral and advanced invasive testing. The Elecsys pTau181 test is intended for adults ages 55 and older with signs, symptoms or complaints of cognitive decline. Clinicians can order the test to help rule out Alzheimer's-related amyloid pathology and identify patients who may benefit from further evaluation.

"Many patients presenting with cognitive symptoms don't have Alzheimer's disease, so helping clinicians rule it out can be just as critical as confirming it," said Dr. Brian Caveney, chief medical and scientific officer at Labcorp. "As a leader in neurology with the broadest portfolio of Alzheimer's tests, Labcorp is proud to make the FDA-cleared Elecsys pTau181 test widely available—helping physicians identify the causes of cognitive decline and guide timely, appropriate care."

Key Features of the Elecsys pTau181 Test
The Elecsys pTau181 test measures phosphorylated Tau (pTau) 181 protein in human plasma, a key biomarker for Alzheimer's pathology, including amyloid plaque and tau aggregate pathology. According to Roche, clinical results demonstrated the test could rule out Alzheimer's pathology with a 97.9% negative predictive value (NPV). A negative test result is consistent with a negative amyloid positron emission tomography (PET) scan result and reduced likelihood that a patient's cognitive impairment is due to amyloid pathology. These patients should be investigated for other causes of cognitive decline. Patients with an initial positive result should be further investigated to determine whether the amyloid pathology can be a cause of cognitive impairment.

Performed via a simple blood draw, the test offers an accessible, more affordable and less invasive alternative to traditional tests such as cerebrospinal fluid (CSF) testing obtained through lumbar puncture and PET scans. Once the test is ordered, the blood draw can be completed in a doctor's office or at any of Labcorp's more than 2,200 patient service centers (PSCs) nationwide.

A Leader in Alzheimer's Testing
Labcorp's announcement underscores the company's commitment to expanding access to blood-based biomarkers for Alzheimer's disease testing. Since March 2023, Labcorp has offered a laboratory-developed test (LDT) version of pTau181, and in October 2023, added it to the company's ATN Profile — a panel combining three key biomarkers to identify and assess biological changes associated with Alzheimer's disease. Most recently, Labcorp launched the FDA-cleared Lumipulse® pTau-217/Beta Amyloid 42 Ratio to aid in the diagnosis of Alzheimer's disease for use in specialty care settings.

For more information about Labcorp's portfolio of tests, visit https://www.labcorp.com/treatment-areas/neurology/conditions/neurodegenerative/alzheimers

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.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements with respect to the expected utility of and benefits to clinicians and patients of the Elecsys pTau181 test.

Each of the forward-looking statements is subject to change based on various important factors, many of which are beyond the company's control. These factors, in some cases, have affected and in the future (together with other factors) could affect the company's ability to implement the company's business strategy, and actual results could differ materially from those suggested by these forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of the forward-looking statements.

The company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Further information on potential factors, risks and uncertainties that could affect operating and financial results is included in the company's most recent Annual Report on Form 10-K under the heading RISK FACTORS and in the company's other filings with the SEC. The information in this press release should be read in conjunction with a review of the company's

filings with the SEC including the information in the company's most recent Annual Report on Form 10-K under the heading "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS".

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