Labcorp Launches First FDA-Cleared Blood Test for Alzheimer's Disease

August 18, 2025

Lumipulse® pTau-217/Beta Amyloid 42 Ratio now available nationwide through Labcorp

BURLINGTON, N.C., Aug. 18, 2025 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, announced today the availability of the Lumipulse® pTau-217/Beta Amyloid 42 Ratio, the first blood-based in-vitro diagnostic (IVD) test cleared by the U.S. Food and Drug Administration (FDA) to aid in the diagnosis of Alzheimer's disease through early detection of the amyloid plaques associated with the disease in appropriate patients. Developed by Fujirebio Diagnostics, Inc., the test is now available nationwide through Labcorp.

The test offers results that are comparable to existing methods that support a diagnosis of Alzheimer's disease – cerebrospinal fluid (CSF) testing obtained through lumbar puncture and positron emission tomography (PET) scans – but from a simple blood draw, making it more affordable, more accessible and less invasive. Fujirebio reports that in clinical studies, the test demonstrated a positive predictive value of 92% and a negative predictive value of 97%.

"The path to an Alzheimer's diagnosis has long meant a diagnostic journey requiring years of invasive procedures and expensive imaging," said Dr. Brian Caveney, chief medical and scientific officer at Labcorp. "Clinicians need better ways to diagnose their patients more quickly, enroll them in clinical trials, or start therapies. By offering this FDA-cleared blood test nationwide, Labcorp is leading the way in delivering innovative solutions for Alzheimer's disease and other neurological conditions by helping patients, families and physicians get answers sooner."

The launch of this test closely follows the release of a new clinical guideline from the Alzheimer's Association, which supports the use of blood-based biomarkers to help evaluate patients suspected of Alzheimer's disease in specialty care settings. The guideline highlights the growing clinical consensus around these tools and reinforces the importance of expanding access.

The Lumipulse pTau-217/Beta Amyloid 42 Ratio is intended for adults aged 50 years and older presenting at a specialized care setting with signs and symptoms of cognitive decline. It is not intended as a screening or stand-alone diagnostic test and must be interpreted in conjunction with other clinical information of the patient. Once ordered, patients can complete the blood draw in a healthcare provider's office or any of Labcorp's more than 2,200 Patient Service Centers (PSCs) nationwide.

The FDA-cleared test builds on and replaces a similar pTau-217/Beta Amyloid 42 Ratio test that the company launched in April 2025.

For more information about Labcorp's portfolio of blood-based biomarkers for Alzheimer's disease and dementia, 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.

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Media, Alissa Lawver, Media@Labcorp.com; Investors, Christin O'Donnell, Investor@Labcorp.com