NEWS RELEASE

Quest Diagnostics to Offer FDA-Cleared Roche pTau217 Blood Test to Assess Alzheimer's Disease Pathology

2026-08-24

Test to join the company's expansive portfolio of Quest AD-Detect® blood tests for assessing symptomatic patients

Quest also launching a new multi-biomarker AD-Detect® lab-developed blood test with low 10% indeterminate rate, so more patients can receive an actionable insight

SECAUCUS, N.J., Aug. 24, 2026 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), a leader in diagnostic information services, today announced two new developments for its Quest AD-Detect® portfolio of blood-based biomarker tests for Alzheimer's disease, with the goal of broadening access to quality blood tests for evaluating symptomatic patients for Alzheimer's disease.

Adding the FDA-cleared Elecsys pTau217 test to the AD-Detect™ portfolio

Earlier today, **Roche announced** that the U.S. Food and Drug Administration (FDA) has cleared the Elecsys® Phospho-Tau (217P) Plasma (pTau217) blood test, making it the first and only FDA-cleared single-assay, single-biomarker blood biomarker test that supports both rule-in and rule-out assessment of amyloid pathology using the same validated clinical cutoffs across primary and specialty care settings. Quest provides a comprehensive menu of blood-based Alzheimer's biomarker tests under the AD-Detect™ brand name. Quest plans to introduce an AD-Detect-branded laboratory test service based on the FDA-cleared Elecsys® pTau217 assay to physicians and clinical trials collaborators nationwide in the fourth quarter of this year. Quest also plans to incorporate the Roche test in future AD-Detect panels in 2027.

"Blood-based biomarker testing has rapidly set a new standard of care for guiding treatment and diagnosis decisions for Alzheimer's disease," said Michael K. Racke, MD, a board-certified neurologist and senior medical director, neurology, Quest Diagnostics. "As one of the pioneers in this field, Quest is constantly looking to add new innovations, both our own and from our collaborators, to our extensive AD-Detect portfolio so that physicians and patients can make the most informed care decisions. As a long-time collaborator with Roche, we look forward to adding the Elecsys® pTau217 to our AD-Detect portfolio, which will give physicians across the U.S. ready access to this important biomarker test."

New AD-Detect multi-biomarker panel with 10% indeterminate rate

Separate from the FDA clearance of the Roche pTau217 test, Quest also announced today it will launch its newest AD-Detect test innovation, AD-Detect® ABeta 42/40, p-tau217, and ApoE Evaluation, lab-developed test for physicians and clinical trials collaborators nationwide at the end of this month. The test provides a score predicting the likelihood of Alzheimer's pathology based on results of pTau217 using a third party in vitro diagnostic as well as results of amyloid beta 42/40 and the APOE isoform (a genetic risk marker) using Quest's highly sensitive mass spectrometry method.

Research published in Neurology® Clinical Practice, a publication of the American Academy of Neurology, demonstrates that the new test aligns with **guidelines from the Alzheimer Association**, which state that blood-based tests that achieve sensitivity and specificity of approximately 90% in the intended use population in specialist settings may be used to confirm a diagnosis of Alzheimer's disease and aid clinical decisions without the need for additional testing. The same research also found that the new test achieved an indeterminate rate of 10%, compared to the 15%-20% rate recommended by the **Global CEO Initiative on Alzheimer's Disease** (CEOi) for a typical clinical population.

"Quest's extensive research demonstrates that blood-based biomarker testing that includes multiple biomarkers may be more sensitive and specific for Alzheimer's pathology and produces a lower rate of indeterminates compared to the same tests performed individually," said Amanda Backner, executive director and general manager, neurology, Quest Diagnostics.

With a physician's order, patients may conveniently provide a blood draw for testing for any AD-Detect test through Quest's patient service center network of approximately 2,000 locations in the U.S., as well as from Quest phlebotomists in physician offices and mobile phlebotomy services.

While positron emission tomography-computed tomography (PET-CT) scan and cerebrospinal fluid (CSF) testing are well established methods for aiding the diagnosis of Alzheimer's disease, may be costly, invasive and difficult to access outside specialty centers. In a study **recently published** in the Journal of Prevention of Alzheimer's Disease,

Quest researchers determined that blood-based biomarker testing was a more efficient and cost-effective method of assessing Alzheimer's pathology in patients with cognitive decline than amyloid PET scans.

For more information on Quest AD-Detect, visit **www.QuestForTheCure.com**.

About Quest Diagnostics

Quest Diagnostics works across healthcare to create a healthier world, one life at a time. We connect people, from clinicians to consumers, with laboratory insights that illuminate a path to better health. With a focus on delivering smarter, simpler testing, we help reveal new avenues to identify and treat disease, empower healthy behaviors and improve healthcare management. Quest Diagnostics serves half the physicians and hospitals in the United States and one in three American adults each year, and our nearly 60,000 employees work together to deliver diagnostic insights that inspire actions to transform lives. **www.QuestDiagnostics.com**

View original content to download multimedia:**https://www.prnewswire.com/news-releases/quest-diagnostics-to-offer-fda-cleared-roche-ptau217-blood-test-to-assess-alzheimers-disease-pathology-302858247.html**

SOURCE Quest Diagnostics