NEWS RELEASE

Quest Diagnostics Launches New AD-Detect™ Blood Test to Aid in Confirming Alzheimer's Disease

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In an oral presentation at the 2025 AAN Annual Meeting, Quest scientists presented data suggesting the test can accurately assess Alzheimer's disease pathology with greater than 90% sensitivity and specificity

SECAUCUS, N.J., April 9, 2025 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), a leader in diagnostic information services, including advanced diagnostics for brain health, today announced the launch of a new laboratory blood test designed to help physicians confirm amyloid brain pathology due to Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or dementia.

The laboratory-developed test, named AD-Detect™ Abeta 42/40 and p-tau217 Evaluation, combines results of blood levels of amyloid beta (AB) 42/40 determined by the company's proprietary tandem mass spectrometry techniques with blood levels of p-tau217 determined by an in vitro immunoassay test. The test results are then used to produce the AD-Detect Likelihood Score™, a composite interpretation created through a proprietary algorithm validated utilizing a well-characterized cohort from the 1Florida Alzheimer's Disease Research Center (ADRC).

The new Quest test panel builds on prior AD-Detect tests that individually assess AB 42/40 and p-tau217, as well as p-tau181 and the ApoE isoform, a genetic risk marker. Those tests help providers assess risk of AD rather than confirm likelihood of amyloid brain pathology due to AD.

"Quest's AD-Detect suite of advanced diagnostics has grown to include a range of validated blood-based biomarkers, giving providers options for personalizing testing for the individual patient," said Kathleen Valentine, Vice President and General Manager, Neurology, Quest Diagnostics. "Quest's innovations in blood testing combined

with our broad patient access are making it easier, faster and more affordable to evaluate patients for AD and other complex diseases."

Research demonstrates test's strong alignment with PET

In AD, a protein called amyloid forms plaques in the brain, triggering changes in another protein, tau, and causing it to twist into tangles. These plaques and tangles disrupt brain cell function while also causing abnormal levels of both proteins to circulate in the blood stream.

In an oral presentation given this week at the American Academy of Neurology (AAN)'s Annual Meeting in San Diego, Quest researchers presented **data** demonstrating that the new test would have a positive predictive value (PPV, the likelihood of disease) of 89% and negative predictive value (NPV, the likelihood there is no disease) of 89% in a population with mild cognitive impairment when the test cut offs were set at 91% sensitivity and 91% specificity. The addition of ApoE, a genetic risk marker, further improved the predictive values. The percentage of patients with likelihood of indeterminate risk was 15%, which decreased to 10% when ApoE test results were included. Importantly, the population was heterogenous and had a low prevalence of beta amyloid PET positivity (39.1% for all patients and 46% for those with MCI or AD), suggesting the test's reliability in a real-world population that includes individuals who do not have AD.

The researchers also categorized 4,326 "real-world specimens" tested by Quest for AB 42/40, p-tau217 and ApoE4 values. The model and cut points categorized these specimens as having 42% high likelihood, 51% low likelihood, and 7% indeterminant likelihood for PET positivity.

"As the population ages and new therapies emerge, our new AD-Detect test will help fill the need for scalable, high-volume solutions that broaden access to robust and affordable evaluation of AD," said study co-author Michael Racke, MD, a board-certified neurologist and Medical Director of Neurology at Quest Diagnostics. "Our new test fulfills acceptable performance criteria set forth by the CEOi. We believe it will give providers greater confidence to move patients with a high likelihood score for AD more quickly on the path to treatment and potentially prevent the use of PET and lumbar puncture in patients whose blood values strongly indicate they do not have AD."

While amyloid PET imaging and cerebral spinal fluid testing are established methods for aiding the diagnosis of AD, they are significantly more expensive, invasive and specialist-dependent than blood-based tests.

The study's strengths included significant ethnic diversity in the population (over 50% Hispanic) while limitations included using a predictive model that did not evaluate performance of the biomarkers in the context of non-AD causes of dementia. The study adds to a growing body of research on the Quest AD-Detect test portfolio, including studies published in the **Journal of Investigative Medicine**, **Frontiers in Neurology** and **Alzheimer's & Dementia**.

Broadening access to quality AD assessment

With the exception of New York, physicians in the United States may now order the test.1 Patients with a physician's order can provide a blood draw for testing through Quest's network of patient sites. Quest maintains approximately 8,000 patient access points, including an extensive patient service center network of approximately 2,000 locations in the U.S., as well as phlebotomists in physician offices and mobile phlebotomy services. Specimens will be transported for testing to Quest's state-of-the-art laboratory in San Juan Capistrano, California.

Nearly **7 million Americans** have Alzheimer's, the most prevalent dementia, a number projected to reach 14 million by 2060. Approximately **12-18% of adults** over the age of sixty are living with mild cognitive impairment, a potential sign of AD. Seventy-seven percent of physicians say new therapies will transform Alzheimer's into a chronic, manageable disease, and 94% of physicians say blood tests would be more cost effective for the healthcare system compared to more invasive methods of detection (e.g., lumbar puncture, imaging studies) according to **a special report from Quest**.

Quest is committed to developing innovative advanced diagnostics to aid in evaluating AD and other brain diseases. For more information, visit **www.QuestForTheCure.com**.

About Quest Diagnostics

Quest Diagnostics works across the healthcare ecosystem to create a healthier world, one life at a time. We provide diagnostic insights from the results of our laboratory testing to empower people, physicians and organizations to take action to improve health outcomes. Derived from one of the world's largest databases of de-identifiable clinical lab results, Quest's diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve healthcare management. Quest Diagnostics annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our nearly 55,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives and create a healthier world. **www.QuestDiagnostics.com**.

1 Except in New York state, where the company plans to apply for approval to offer the test clinically.

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