# FDA Clears First Blood Test for Alzheimer's Diagnosi

## — Plasma assessment is not intended as a screening or stand-alone diagnostic test, agency says

by Judy George, Deputy Managing Editor, MedPage Today
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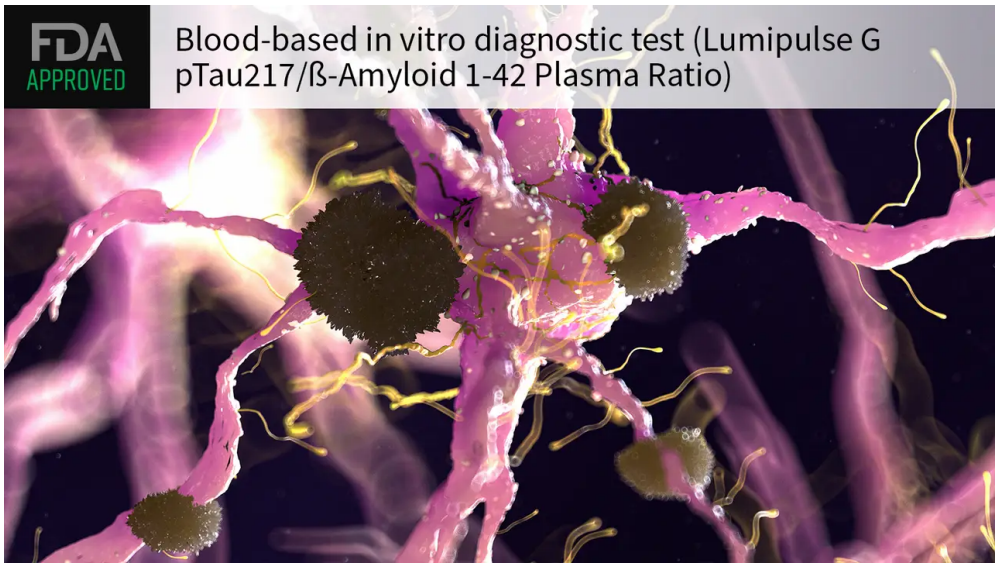


The FDA cleared the first blood-based in vitro diagnostic test for Alzheimer's disease, the agency announced Friday.

The blood test, known as the Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio, can be used to detect amyloid plaques associated with Alzheimer's in people ages 55 and older who have signs and symptoms of the disease, the agency said.

"Alzheimer's disease impacts too many people, more than breast cancer and prostate cancer combined," FDA Commissioner Martin Makary, MD, MPH, said in a statement. "Knowing that 10% of people aged 65 and older have Alzheimer's, and that by 2050 that number is expected to double, I am hopeful that new medical products such as this one will help patients."

The test measures phosphorylated tau 217 (p-tau 217) and beta-amyloid 1-42 concentrations in plasma to help detect amyloid plaques associated with Alzheimer's disease. It combines these concentrations into a numerical ratio of p-tau 217/beta-amyloid 1-42 to identify

patients with amyloid pathology, reducing the need for a PET scan or cerebrospinal fluid (CSF) analysis.

The FDA's decision was based on a clinical study of 499 individual plasma samples from adults who were cognitively impaired. The test results were validated against amyloid PET or CSF tests and showed a 91.7% positive predictive value and 97.3% negative predictive value. Less than 20% of the 499 patients tested received an indeterminate result.

These findings indicate that the new blood test can reliably predict the presence or absence of amyloid pathology associated with Alzheimer's disease at the time of the test in patients who are cognitively impaired, the FDA said.

The test is intended for patients presenting at a specialized care setting with signs and symptoms of cognitive decline, the agency emphasized. Results must be interpreted in conjunction with other patient clinical information.

Risks associated with the blood test are the possibilities of false positive and false negative test results, which could lead to inappropriate diagnosis, unnecessary or delayed treatment, and psychological distress.

"Importantly, the Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio is not intended as a screening or stand-alone diagnostic test and other clinical evaluations or additional tests should be used for determining treatment options," the FDA said.

A number of laboratory-developed tests on the market can be used to detect blood-based biomarkers associated with Alzheimer's disease, but this is the first test cleared by the FDA.

In 2022, the Alzheimer's Association published appropriate use recommendations for Alzheimer's blood biomarkers. The group plans to announce new clinical practice guidelines for using blood tests in specialty care settings this summer.

More than 7 million older adults in the U.S. have Alzheimer's disease, according to the most recent Alzheimer's Association figures, and the number is expected to grow.

"The FDA clearance of a first blood test, the Lumipulse plasma assay, to detect Alzheimer's marks a major milestone for patients and clinicians, and comes at a pivotal time as the number of people developing the disease continues to increase exponentially," noted

Howard Fillit, MD, chief science officer of the Alzheimer's Drug Discovery Foundation in New York City.

"The ability to diagnose Alzheimer's earlier with a simple blood test -- like we do for cholesterol -- is a game-changer, allowing more patients to receive treatment options that have the potential to significantly slow or even prevent the disease," Fillit said.

In 2022, the FDA issued clearance for the Lumipulse G β-Amyloid Ratio -- the first in vitro diagnostic to measure amyloid in CSF -- to Fujirebio Diagnostics in Japan, the same company that makes the newly cleared blood test.

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Judy George covers neurology and neuroscience news for MedPage Today, writing about brain aging, Alzheimer's, dementia, MS, rare diseases, epilepsy, autism, headache, stroke, Parkinson's, ALS, concussion, CTE, sleep, pain, and more. Follow

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**Disclosures**
The Alzheimer's Drug Discovery Foundation provided translational research funding for this assay to Fujirebio Europe.

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