

FDA Greenlights First Alzheimer's Blood Test:

What You Should Know

In May 2025, The U.S. Food and Drug Administration (FDA) approved the first blood test to assist in the diagnosis of Alzheimer's disease. Although this is a major development, it's important to understand how the test works, who it's for and what are the limitations.

Frequently Asked Questions: A Q&A with Dr. Dung Trinh

1 What is this test and how does it work?

The Lumipulse G pTau217/ β -Amyloid 1-42 Plasma Ratio Test, developed by Fujirebio Diagnostics, is the first FDA-cleared blood test designed to help detect Alzheimer's disease. It measures two proteins in the blood: phosphorylated tau (pTau217) and beta amyloid 1-42. These proteins are involved in the formation of amyloid plaques and tau tangles—key hallmarks of Alzheimer's disease. The test calculates a ratio between the two to determine whether a person likely has these brain changes. It offers a much less invasive alternative to traditional methods like PET scans and spinal taps.

2 Who should consider getting it?

This test is intended for **adults aged 55 and older** who are **already showing signs or symptoms of cognitive decline**. It is designed to support, **not replace**, a comprehensive evaluation by a healthcare provider.

3 Are there any limitations to consider?

Yes. While the Lumipulse test is a valuable tool, **it is not** a standalone diagnostic and should be interpreted in the context of a full clinical evaluation. It is not intended for screening asymptomatic individuals, and like any test, there is a risk of false positives or false negatives. A positive result **doesn't guarantee** a diagnosis of Alzheimer's, and a negative result doesn't rule it out entirely. Decisions about diagnosis and treatment **should be made in consultation** with a specialist who can integrate all aspects of a patient's health history, cognitive assessment, and other tests.

Worried about memory loss?

You're not alone. Alzheimer's Orange County is here to help. Seek local support and find resources and services that can make a life-transforming difference to improve your quality of life.

