

Alzheimer's Blood Tests:

What You Should Know

In May 2025, the FDA cleared the Fujirebio blood test, and in October 2025, cleared the Roche blood test, both to assist clinicians in evaluating Alzheimer's disease-related pathology. Although these are major developments, it is important to understand how the tests work, who they are for, and what their limitations are.

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

1 What are these tests and how do they work?

The Lumipulse G pTau217/beta-Amyloid 1-42 Plasma Ratio Test, developed by Fujirebio Diagnostics, measures pTau217 and beta-amyloid 1-42 and combines the results into a ratio that helps estimate whether amyloid pathology is likely. The Roche Elecsys Phospho-Tau (181P) Plasma test measures pTau181 alone. A negative Roche result is consistent with a negative amyloid PET scan and a reduced likelihood that cognitive impairment is due to amyloid pathology; a positive result requires further evaluation. Both are blood tests and are less invasive than PET imaging or a lumbar puncture.

In Roche's FDA clinical study, the negative predictive value was 97.9% in a 312-person, low-prevalence population reflective of primary care.

2 Who should consider getting them?

These tests are intended for people who are already experiencing cognitive decline, not for routine screening of people without symptoms. Fujirebio's test is indicated for adults age 50 and older in a specialized care setting. Roche's test is indicated for adults age 55 and older who have signs, symptoms, or complaints of cognitive decline and is intended to aid the initial assessment.

3 Are there any limitations to consider?

Yes. While these tests can provide useful information, neither is a stand-alone diagnosis of Alzheimer's disease. Results should be interpreted with a full clinical evaluation, including the patient's history, cognitive assessment, and other testing when appropriate. False-positive and false-negative results can occur. A positive result does not by itself establish Alzheimer's disease, and a negative result does not rule out every possible cause of cognitive decline. Diagnosis and treatment decisions should be made with a qualified healthcare professional.

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.

