

Alzheimer's Blood Tests

THE TWO TESTS

	Fujirebio Diagnostics	Roche Diagnostics
FDA STATUS	Cleared May 16, 2025	Cleared October 8, 2025
INTENDED USE	Aid in identifying amyloid pathology associated with Alzheimer's disease. Adults age 50+ with signs and symptoms of cognitive decline in a specialized care setting.	Aid in the initial assessment for Alzheimer's disease and other causes of cognitive decline. Adults age 55+ with signs, symptoms, or complaints of cognitive decline.
ANALYTES	pTau217 and beta-amyloid 1-42	pTau181
OUTPUT	pTau217/beta-amyloid 1-42 ratio with dual cutoffs: negative, indeterminate, or positive for likelihood of amyloid pathology.	Single-assay pTau181 result. A negative result is consistent with a negative amyloid PET result; an initial positive result requires further investigation.
CLINICAL STUDY	499 participants. Positive-result predictive value 91.8%; 2.7% of negative results were amyloid-positive; 19.6% of results were indeterminate.	312 participants in a low-prevalence population reflective of primary care. NPV 97.9%; PPV 22.4%; amyloid-PET positivity prevalence 13.1%.
TURNAROUND	Laboratory-based analysis	Laboratory-based analysis

Intended use: adjunct to clinical assessment; neither test is a stand-alone Alzheimer's diagnosis or screening test.

APPLIES TO BOTH TESTS

Who May Be Appropriate for Testing

- People with cognitive symptoms who meet the test-specific age and care-setting indication
- Not intended for asymptomatic individuals or general screening

Clinical Utility

- Less invasive than lumbar puncture or PET imaging
- Can support diagnostic evaluation and decisions about referral or additional testing

Limitations

- Not intended for use in isolation
- False-positive and false-negative results can occur
- Interpret results with the broader clinical context and current test labeling

Special thanks to Dr. Dung Trinh, Chief Medical Officer, Healthy Brain Clinic, for his contributions to this handout

When to Consider Ordering

- ✓ Symptomatic patient who meets the specific test's FDA-labeled age and care-setting criteria
- ✓ After cognitive history and assessment when amyloid pathology is part of the differential diagnosis
- ✓ When a blood biomarker result could help guide referral or the need for PET/CSF testing
- ✗ Asymptomatic screening
- ✓ Unclear diagnosis after initial clinical work-up

Documentation Tips

- Include cognitive history and relevant functional changes
- Include cognitive assessment information
- Document the clinical question and how the result will guide next steps
- Use results to guide, but not replace, diagnosis
- Follow current FDA labeling and laboratory-specific instructions for the assay ordered

Additional Resources

- FDA 510(k) database: K242706 (Fujirebio) and K252163 (Roche)
- Fujirebio: [fujirebio.com](https://www.fujirebio.com)
- Roche: [diagnostics.roche.com](https://www.diagnostics.roche.com)

Is Your Patient Experiencing Memory Loss?

Alzheimer's Orange County (AlzOC) provides a comprehensive family of programs designed to meet Orange County residents affected by memory loss wherever they are in their journey. Whether your patient is focused on brain health, has just received a diagnosis, or is progressing through later stages, we are committed to helping them live well.

HOW WE HELP

- | | |
|----------------------------|-----------------------------|
| • Memory Screenings | • Support Groups |
| • Helpline | • Early Memory Loss Support |
| • Care Consultations | • Multilingual Support |
| • Community Education | • Interfaith Outreach |
| • Adult Day Services | • Social and Art Programs |
| • Enhanced Care Management | |