

Alzheimer’s Blood Test: Physician Fact Sheet

Source: Dr. Dung Trinh | Chief Medical Officer, Healthy Brain Clinic

Overview <ul style="list-style-type: none">Developer: Fujirebio DiagnosticsFDA Status: Cleared in May 2025Indication: Detects amyloid plaques by measuring pTau217 and beta-amyloid 1-42Use: Adjunct to clinical assessment in patients with cognitive symptoms	Who is Eligible for Testing <ul style="list-style-type: none">Adults ≥ 55 yearsExhibiting signs or symptoms of cognitive impairmentNot intended for asymptomatic individuals or general screening
Test Mechanism <ul style="list-style-type: none">Analytes: pTau217 and beta-amyloid 1-42Output: Ratio correlates presence of amyloid plaquesTurnaround: Laboratory-based analysis	Accuracy <ul style="list-style-type: none">Validated in 499 participants~92% sensitivity, ~97% specificity vs CSF or PET scans
Clinical Utility <ul style="list-style-type: none">Less invasive and more accessible than lumbar puncture or PET scanSupports diagnosis alongside clinical and cognitive assessment	Limitations <ul style="list-style-type: none">Not intended for use in isolationFalse positives and negative can occurInterpret results with broader clinical context
When to Consider Ordering <ul style="list-style-type: none">✔ Patient ≥55 with memory loss✔ Before more invasive Lumbar Puncture or PET scan✖ Asymptomatic screening✔ Unclear diagnosis after initial work-up	Documentation Tips <ul style="list-style-type: none">Include cognitive historyInclude cognitive assessment informationUse results to guide but not replace diagnosis

Additional Resources

- FDA: www.fda.gov/news-events/press-announcements
- Fujirebui: www.fujirebio.com