

Simple Blood Test. Timely Insights.

Improved Diagnostic Clarity for Patients with Cognitive Decline

Lumipulse® G pTau 217/β-Amyloid 1-42 Plasma Ratio Test

The First FDA-cleared Blood Test for Patients Being Assessed for Alzheimer's Disease

- Earlier detection of amyloid pathology in patients presenting with cognitive decline
- Improves access to amyloid testing with a simple blood draw and automated immunoassay
- Combines pTau 217 and β-Amyloid 1-42 for greater accuracy in identifying amyloid positron emission tomography (PET) positivity than plasma pTau 217 alone[1]
- Lowers costs compared to PET scan and is less invasive than cerebral spinal fluid (CSF)

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Unprecedented Access to Objectively Assess Patients with Cognitive Decline

In the early stages of Alzheimer's disease (AD), relying solely on cognitive tests to assess patients may result in incorrectly classifying 50-60% of patients.[2,3]

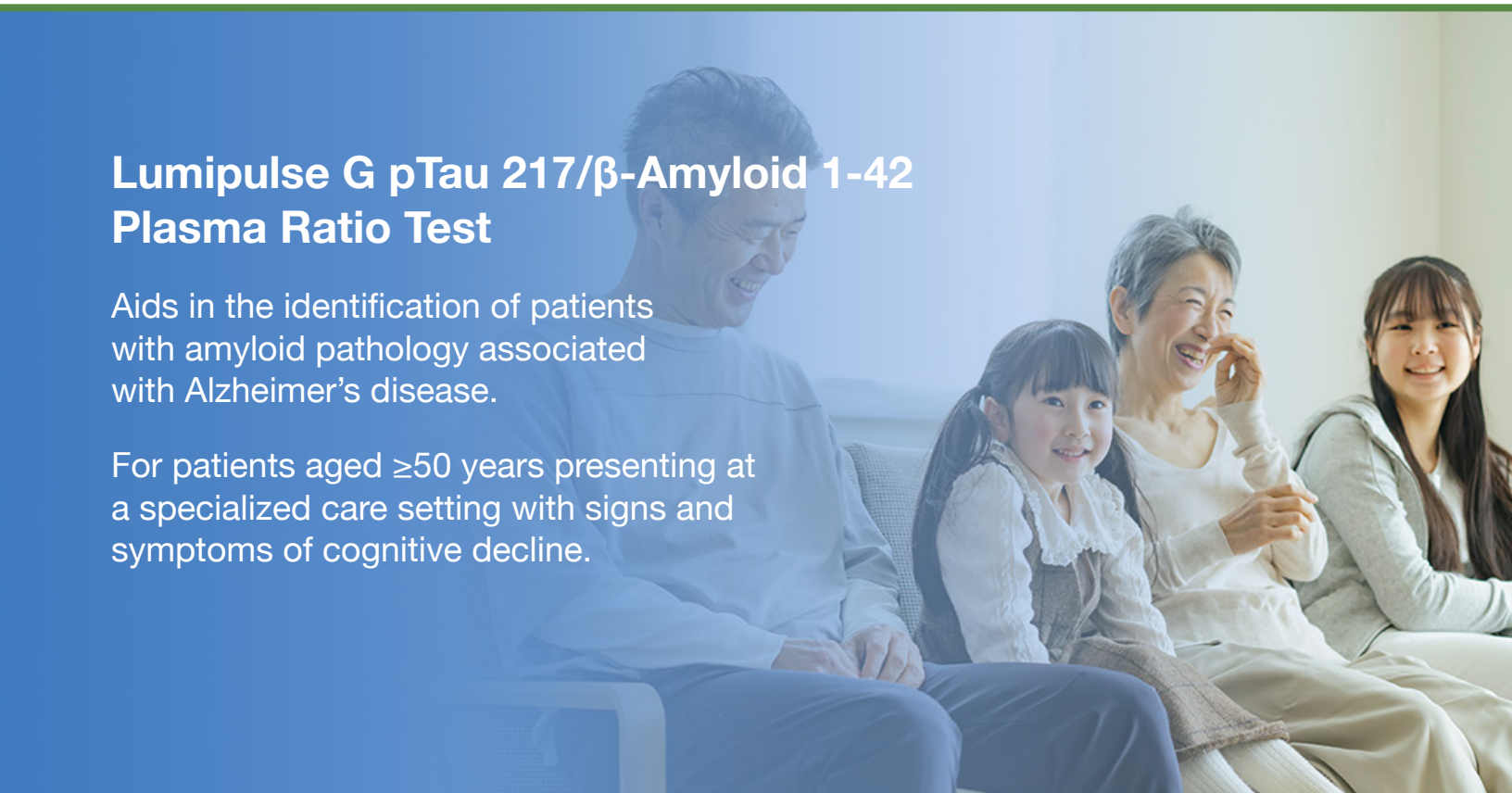
PET imaging is expensive and often inaccessible to many individuals and their caregivers. CSF biomarkers also present practical barriers that limit their broad use.[4]

Blood-based biomarkers allow specialized providers early and accurate assessments of patients with cognitive decline.[5,6]

With high positive and negative predictive values, a blood test can accurately detect amyloid pathology, allowing healthcare providers to offer answers and guidance when addressing cognitive impairment concerns.[7]

An objective, early diagnosis helps providers, patients, and families explore care options earlier and improve treatment outcomes.[8-10]





Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio Test

Aids in the identification of patients with amyloid pathology associated with Alzheimer's disease.

For patients aged ≥50 years presenting at a specialized care setting with signs and symptoms of cognitive decline.

Clinical Test Performance

The pTau 217/β-Amyloid 1-42 Plasma Ratio results are highly concordant with amyloid PET imaging and amyloid CSF ratio results.

92% of individuals with a **positive** result have a **positive** CSF or amyloid PET scan result

97% of individuals with a **negative** result have a **negative** CSF or amyloid PET scan result

Result Interpretation

PLASMA SAMPLE

In patients aged ≥50 years presenting at a specialized care setting with signs and symptoms of cognitive decline, results should be interpreted as follows:

RESULT	RATIO INTERPRETATION*		PREDICTIVE VALUE (95% CI)
≥0.00738	POSITIVE	Consistent with patients **LIKELY** to have amyloid pathology. Result does not establish a diagnosis of AD or other cognitive disorders.	PPV **91.8%** (87.8%-94.6%)
0.00371 - 0.00737	INDETERMINATE**	Consistent with patients **UNCERTAIN** to have amyloid pathology. Consider further testing.	
≤0.00370	NEGATIVE	Consistent with patients **UNLIKELY** to have amyloid pathology. Should investigate for other causes of cognitive decline.	NPV **97.3%** (93.9%-98.8%)

*Test results must be interpreted in conjunction with other patient clinical information. This test is not intended as a screening or stand-alone diagnostic assessment.

**19.6% of patients had an indeterminate result in the clinical study that supported the FDA clearance.

PPV, positive predictive value; NPV, negative predictive value

Download a digital copy of the Result Interpretation Guide

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Rationale for pTau 217/β-Amyloid 1-42 Plasma Ratio

The phosphorylated tau at threonine 217 (pTau 217) to Amyloid β-Peptide (1-42) (β-Amyloid 1-42) ratio is an innovative multi-analyte and highly sensitive blood-based biomarker for the detection of AD.[11,12]

The combination of pTau 217 and β-Amyloid 1-42 plasma as a ratio was shown to have high accuracy in detecting discriminative Aβ-PET positivity compared to plasma pTau 217 alone, including prodromal AD.[1]

Cartridge-based ratio testing on the fully automated Lumipulse G1200 platform offers fast, scalable, high-quality results for comprehensive and cost effective AD assessments.

Blood testing reduces concerns related to PET imaging radioactivity and the invasiveness of CSF collection.

Neurodegenerative Diagnostics with the LUMIPULSE G1200 System



- Fully automated with random access
- 120 tests/hour
- Small footprint
- Individual test cartridges to eliminate reagent waste
- Accurate and precise test results

PRODUCT	CONFIGURATION	PART NUMBER
AUTOMATED IMMUNOASSAY INSTRUMENT		
LUMIPULSE G1200	1 System, Dimensions 3.9’ x 2.6’ x 4.8’	234259
IN VITRO DIAGNOSTIC USE, LUMIPULSE G PTAU 217/β-AMYLOID 1-42 PLASMA RATIO		
Test Principle	Chemiluminescent Enzyme Immunoassay	
Sample Type	K_2EDTA Plasma	
Test Time	30 minutes to first test	
Measuring Range	pTau 217: 0.047 pg/mL to 10.000 pg/mL β-Amyloid 1-42: 0.8 pg/mL to 500.0 pg/mL	
Limit of Blank, Limit of Detection, Limit of Quantification	pTau 217: 0.025 pg/mL, 0.0407 pg/mL, 0.0472 pg/mL β-Amyloid 1-42: 0.128 pg/mL, 0.2074 pg/mL, 0.8000 pg/mL	
pTau 217 Plasma Immunoreaction Cartridges	3 x 14 cartridges	81550
pTau 217 Plasma Calibrator	1 x 1.5 mL, 5 concentrations	81557
pTau 217 Plasma Control	2 x 1.5 mL, 2 concentrations	81558
β-Amyloid 1-42 N Plasma Immunoreaction Cartridges	3 x 14 cartridges	235447
β-Amyloid 1-42 N Plasma Calibrator	1 x 1.5 mL, 4 concentrations	235454
β-Amyloid 1-42 N Plasma Control	2 x 1.5 mL, 2 concentrations	81559

For more information on the FDA-cleared Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio Test, visit fujirebio.com or contact neuro@FDI.com

The Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio must be calculated using the results obtained from Lumipulse G pTau 217 Plasma and Lumipulse G β-Amyloid 1-42-N Plasma on the same patient sample and same LUMIPULSE G1200 analyzer. Use of another manufacturer’s assays may result in significantly different ratios. pTau 217 and β-amyloid 1-42 values determined on patient samples using other manufacturers’ assays cannot be interchangeably used to calculate the Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio which could lead to wrong diagnostic conclusions. The Lumipulse G pTau 217 Plasma assay should only be used with the Lumipulse G β-Amyloid 1-42-N Plasma assay to calculate the ratio of pTau 217/β-amyloid 1-42. The Lumipulse G pTau 217 Plasma and the Lumipulse G β-Amyloid 1-42-N Plasma assays are not intended to be used individually.

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