Lumipulse® G pTau217/β-Amyloid 1-42 Plasma Ratio Test

Improved Diagnostic Clarity for Patients with Cognitive Decline

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

Refer to the test Instructions for Use for complete instructions and all product information.

For additional clinical tools and resources, 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.

FUJIREBIO

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Lumipulse® G pTau217/β-Amyloid 1-42 Plasma Ratio Test

Sample Collection, Storage, Handling and Testing Recommendations

Refer to the test **Instructions for Use** for complete instructions and all product information.

Fresh specimens recommended. Results may be affected by erythrocytes, fibrin, or other unspecified precipitates or debris contained in specimens.

TEMPERATURE	2 to 8°C	-30 to -10°C	-60°C	On-board
STABILITY	24 Hours	1 Month	1 Month	3 Hours

SAMPLE COLLECTION

K_2EDTA tube

SAMPLE PROCESSING

≤2 HOURS OF COLLECTION

- Keep at room temperature (RT, 23-28°C)
- **Centrifuge:** RT for 10 mins @ 2000 x g

NOTE: Specimens degrade rapidly at RT; do not store >2 hours or ship at RT.

STORAGE

TESTING ≤2 HOURS

- Keep at RT (23-28°C)
- Immediately proceed to **Measurement**

TESTING >2 HOURS

Transfer to polypropylene storage tubes

≤24 Hours (Refrigerate)
Store/Transport: 2-8°C

>24 Hours – 1 Month (Freeze)
Store: ≤-60°C, **Transport:** Dry ice

SAMPLE PREPARATION (REFRIGERATED OR FROZEN)

Refrigerated samples, bring to RT (23-28°C).
Frozen samples, thaw at room temperature for ≥45 minutes.
NOTE: Avoid >3 freeze/thaw cycles.

- **Vortex:** ≥10 seconds
- **Centrifuge:** RT for 5 mins at 2000 x g
- **Measure:** immediately

MEASUREMENT

Dispense the specified plasma volume to the sample cup or tube.

- **pTau 217:** 100 µL
- **β-Amyloid 1-42-N:** 80 µL

