

Patient ID SA00172439	Patient Name TESTING, B217P N	Birth Date 1961-02-25	Sex F	Age 63
Order Number SA00172439	Client Order Number SA00172439	Ordering Physician CLIENT,CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 21 Oct 2024 08:00		

Phospho-Tau 217, P

pTau217, P

<0.050 pg/mL

REFERENCE VALUE

Negative: ≤ 0.185 pg/mL

Intermediate: 0.186–0.324 pg/mL

Positive: ≥ 0.325 pg/mL

pTau217 Interpretation

A normal (negative) pTau217 result is consistent with a negative (normal) amyloid positron emission tomography (PET) scan result. This result indicates a reduced likelihood that an individual has neuropathological changes associated with Alzheimer's disease.

Clinical performance of this test was established in a study of 427 individuals, 50 years and older, with mild cognitive impairment or early dementia. The prevalence of amyloid

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pathology was 64% as defined by amyloid-PET and a Centiloid of ≥ 25. For detection of an abnormal amyloid-PET, the test sensitivity at the lower cutpoint (≤ 0.185 pg/mL) was 92% and the specificity at the upper cutpoint (≥ 0.325 pg/mL) was 96%.

The diagnostic performance of this test has not been established in asymptomatic individuals. Elevations of pTau217 may be seen in individuals with impaired kidney function associated with chronic kidney disease and should be interpreted with caution in these situations.

The testing method is a chemiluminescent enzyme immunoassay manufactured by Fujirebio, Inc. and performed on the Lumipulse analyzer. Values obtained with different assay methods or kits may be different and cannot be used interchangeably.

This test is not intended as a screening or standalone diagnostic assay; correlation with clinical findings is recommended.

Received: 22 Oct 2024 10:08

Reported: 22 Oct 2024 10:16

Laboratory Notes

- 1 This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
SDL	Mayo Clinic Laboratories - Rochester Superior Drive	3050 Superior Drive NW, Rochester MN 55905	Nikola Baumann Ph.D.	24D1040592