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Patient Name: pTau217, Test	Physician: Not a Provider, Validation and Testing
Patient ID: E41	Facility: Validation Runs and Testing
Date of Birth: 02/02/1965 (60 Y)	Date Collected: 02/27/2025 08:36 PT
Patient Phone: (360) 543-6844	Received: 02/27/2025 08:38 PT
Patient Address: 3548 MERIDIAN ST Suite 101 BELLINGHAM	Released: 02/27/2025 08:39 PT
Address: 98225 WA	Sample: E87
Requisition: NM00000087	Specimen Type: Plasma

Plasma pTau-217			
Test	Result	Reference	Units
Plasma pTau-217	0.3	<0.34	ng/L
INTERPRETATION <p>A test result ≤ 0.34 ng/L is a negative result and is consistent with a negative amyloid positron tomography (PET) scan. A negative result indicates a low likelihood that a patient's cognitive impairment is due to Alzheimer's disease (AD) with 95% negative predictive value. A test results between 0.34 and 0.63 ng/L is considered intermediate. An intermediate results does not establish a diagnosis of AD or other cognitive disorder and has increased uncertainty in regard to amyloid positivity. A test result ≥ 0.63 ng/L is positive and is consistent with a positive PET scan with 95% predictive value. A positive result does not independently establish a diagnosis; results should be interpreted in the context of other clinical signs and symptoms of AD. This test is a single molecule assay powered by Simoa® using the ALZpath Dx antibody to p-Tau217 developed by ALZpath Inc. This is a laboratory developed test (LDT) whose performance characteristics were determined by Neurocode USA, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. The laboratory is regulated under CLIA to perform high-complexity testing. p-Tau results obtained by different methods cannot be used interchangeably.</p> LIMITATIONS <p>Test is intended to be used on adult patients, ages 45 years and older, presenting with cognitive impairment who are being evaluated for AD and other causes of cognitive decline. There are comorbid conditions that may affect phosphorylated tau levels in blood. These can include conditions affecting hepatic and renal function, such as chronic kidney disease (CKD), as well as a history of stroke or myocardial infarction. Certain medications to support kidney function may also play a role in heightened levels of p-Tau217. Additionally, differences in results based on racial and ethnic background, sex, and age have not been established.</p> BACKGROUND <p>Alzheimer's disease (AD) is a neurodegenerative disorder hallmarked by extracellular amyloid plaques and intraneuronal neurofibrillary tangles of phosphorylated Tau (p-Tau) in the brain. The tau protein normally maintains microtubules assembly and stability of neuronal axons; however, tau protein with excessive phosphorylation can have pathological consequences. In patients with AD, aggregates of p-Tau can be detected by postmortem neuropathology evaluation or pre-mortem positron tomography (PET) imaging with specific tracers. Soluble p-Tau also accumulates in the CSF and can be detected in lumbar puncture samples, and ultra-sensitive methods including the technique used here can accurately detect p-Tau levels in the blood, which correlate well with CSF levels and with brain amyloid plaque burden. Plasma p-tau217 levels correlate with amyloid-PET imaging and are more sensitive and specific than p-tau181 in distinguishing AD from other neurodegenerative disorders.</p> REFERENCES <p>Ashton et al., 2024. Diagnostic Accuracy of a Plasma Phosphorylated Tau 217 Immunoassay for Alzheimer Disease Pathology. JAMA Neurology. https://doi.org/10.1001/jamaneurol.2023.5319. Revised Criteria for Diagnosis and Staging of Alzheimer's Disease: Alzheimer's Association Workgroup. NIA-AA. Draft body text as of October 9, 2023. Noble, W., Hanger, D. P., Miller, C. C. J. & Lovestone, S. The Importance of Tau Phosphorylation for Neurodegenerative Diseases. Front. Neurol. 4, 83 (2013). Telser, J., Risch, L., Saely, C. H., Grossmann, K. & Werner, P. P-tau217 in Alzheimer's disease. Clin. Chim. Acta 531, 100–111 (2022). Berry, K. et al. Hepatic and renal function impact concentrations of plasma biomarkers of neuropathology. Alzheimers Dement. Diagn. Assess. Dis. Monit. 14, e12321 (2022). Mielke, M. M. et al. Performance of plasma phosphorylated tau 181 and 217 in the community. Nat. Med. 28, 1398–1405 (2022). Gouda, M., Antwi-Berko, D., van Leeuwenstijn, M.S.S.A., Hussainali, Z., Bongers, B., Vanbrabant, J., in 't Veld, S.G.J.G., Edelmayr, R.M., Stoops, E., Jeromin, A., Teunissen, C.E., Verberk, I.M.W., 2023. Plasma phosphorylated tau 217 levels are highly stable under common pre-analytical sample handling procedures. Alzheimer's & Dementia 19, e078393. https://doi.org/10.1002/alz.078393</p>			