

Neurocode, p-Tau217^a
Alzheimer's disease diagnosis

Context for performance data:

Plasma p-tau217 measured using a high-sensitivity single-molecule assay (SIMOA) method developed by ALZpath for the Quanterix HD-X analyzer. Samples were analyzed at Neurocode CLIA-licensed laboratory in Bellingham, WA and validated as a laboratory developed test for clinical use. Two independent cohorts were used to determine the cut-offs: Wake Forest ADRC cohort and University of British Columbia (UBC) CARD. Wake Forest ADRC study is a diverse community-based cohort with amyloid status determined by Aβ-PET+ defined by centiloid ≥ 24 .^b UBC-CARD is two sub-studies where amyloid status was determined either by CSF Aβ42/40 ratio or neuropathology confirmation post-mortem.^c Comorbidity data was collected, with an impact observed for BMI and chronic kidney disease ($p < 0.001$).

		CEOi BBM Workgroup Recommendations ¹		Wake Forest ADRC ^d <i>Link^b</i>		UBC-CARD CSF Aβ42/40 ^e <i>Link^c</i>	UBC-CARD neuropathology ^e <i>Link^c</i>
		Triage	Confirmatory				
Performance	Cutoffs ^f			0.460 pg/mL	Negative: ≤ 0.365 pg/mL Intermediate: 0.366-0.548 pg/mL Positive: ≥ 0.549 pg/mL	Negative: ≤ 0.34 ng/L Intermediate: 0.35-0.62 ng/L Positive: ≥ 0.63 ng/L	Negative: ≤ 0.34 ng/L Intermediate: 0.35-0.62 ng/L Positive: ≥ 0.63 ng/L
	Sensitivity (%)	≥90%	≥90%	90.4%	94.5%	94%	96%
	Specificity (%)	≥75% (secondary care) ≥85% (primary care)	≥90%	92.6%	95.6%	94%	95%
	Participants with intermediate results (%)			NA	12%	16%	20%
	Prevalence of amyloid in study population (%)			51.8%		65%	61%
	Positive predictive value (PPV) ^g (%)			93.0%	95.0%	96%	97%
	Negative predictive value (NPV) ^g (%)			90.0%	93.3%	90%	91%
	Reference standard			Amyloid PET		CSF Aβ42/40	Neuropathology
Study Population	Sample size (N)			141		51	115
	Age (mean)			70.43		67.4	71.8
	Diagnosis of study population (n)			MCI (106), dementia (35)		Non-AD dementia (14), MCI (13), AD (26)	Non-AD dementia (45), AD (70)
	Sex (% female)			49%		53%	47%
	Race (% nonwhite)			13.4%		Not available	Not available
	Ethnicity (% hispanic/latino)			2.1%		Not available	Not available
	Years of education (mean)			15.73		Not available	Not available

Limitations: Plasma p-tau217 is intended to be used in adult patients, aged 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 the 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 pTau217. Additionally, differences in results based on racial and ethnic background, sex, and age have not yet been established. 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 with different methods cannot be used interchangeably.

Access: Test is currently available, and all testing is conducted at Neurocode's CLIA/CAP laboratory. Our list price is \$349 and billed to insurance with CPT code 0479U.

^aALZpath assay; ^bData has been reanalyzed by Wake Forest ADRC to exclude cognitively impaired individuals; ^cUCB-CARD data has been reanalyzed by Neurocode to exclude cognitively unimpaired individuals; ^dCommunity-based cohort; ^eMemory clinic setting; ^fDetermined during study; ^gPPV/NPV at prevalence of amyloid in study population. Aβ-PET, amyloid beta positron emission tomography; AD, Alzheimer's disease; ADRC, Alzheimer's Disease Research Center; BMI, body mass index; CAP, College of American Pathologists; CARD, Center for Alzheimer's Disease and Related Disorders; CLIA, Clinical Laboratory Improvement Amendments; CSF, cerebrospinal fluid; MCI, mild cognitive impairment. 1. Schindler et al., Nature Reviews Neurology. 2024.