

Alzheimer's Disease Biomarkers

Alzheimer's Disease (AD) is the most common form of dementia, affecting an estimated 6.7 million people in the United States (1). The defining neuropathologies of AD are extracellular A β -plaques and intracellular neurofibrillary tangles (NFTs). Newly-proposed guidelines from the *Alzheimer's Association* now recommend the use of blood-based biomarker tests as a more affordable and accessible AD diagnostic aid (2). Neurocode is a CAP-accredited CLIA-certified laboratory in Bellingham, WA USA specializes in AD fluid biomarker testing.

Neurocode Alzheimer's Disease Biomarkers

Test Name	Matrix	Platform / Methodology	Intended Use
Phosphorylated Tau 217 (ALZpath Dx pTau-217)	Plasma	Quanterix SIMOA / Lumipulse CLEIA	LDT for clinical use & clinical trial research
Neurofilament light chain (Nf-L)	Plasma or Serum	Lumipulse CLEIA	LDT for clinical use & clinical trial research
Glial fibrillary acidic protein (GFAP)	Plasma	Lumipulse CLEIA	LDT for clinical use & clinical trial research
Amyloid β 42/40 (A β 42/40)	Plasma	Quanterix SIMOA	Clinical trial research
Total Tau, amyloid β 42/40 (A β 42/40), pTau-181, and Nf-L	CSF	Lumipulse CLEIA	IVD & LDTs for clinical use & clinical trial research

Analytical and clinical performance determined at Neurocode laboratory per CLSI guidelines.

pTau-217 - Plasma pTau-217 levels correlate with tau-PET imaging and are more sensitive and specific than pTau-181 in distinguishing AD from other neurodegenerative disorders. Clinical performance was determined using plasma samples from amyloid PET(+) and (-) subjects.

AMR (ng/L)	AUC	Cut-off (ng/L)	Specificity	Sensitivity	Stability
0.007 - 10	0.95	0.63	95.3%	95.8%	≤ 48 hours 37°C ≤ 1 week 21°C ≤ 1 week 4°C ≤ 4 weeks -20°C ≤ 8 months -80°C ≤ 5 F/T cycles

Nf-L - Nf-L is a nonspecific biomarker for axonal degeneration; elevated Nf-L levels are associated with a range of neurological disorders including AD, ALS, MS, FTD, and TBI.

AMR (ng/L)	Precision	Accuracy	Age	Reference range (ng/L)	Stability
2.0 - 741.6	$\leq 10\%$ intra-laboratory	95%	20 - 29 30 - 39 40 - 49 50 - 59 60 - 69 70 - 79 ≥ 80	≤ 8.4 ≤ 11.4 ≤ 15.4 ≤ 20.8 ≤ 28.0 ≤ 37.9 ≤ 51.2	≤ 1 week room temp ≤ 1 week 4°C ≤ 1 week -20°C ≤ 6 months -80°C ≤ 5 F/T cycle

GFAP - GFAP is a biomarker of astrocyte activation, which occurs in response to many CNS pathologies including stroke, TBI, and neurodegenerative diseases including AD; GFAP can provide valuable information for differential diagnosis.

Precision	AUC	Age	Reference range (ng/L)	Stability
≤ 3% intra-laboratory	0.96 Aβ PET+ vs HC	<60 60 - 69 ≥ 70	≤ 48.2 ≤ 64.9 ≤ 90.7	≤ 1 week room temp ≤ 1 week 4°C ≤ 3 weeks -20°C ≤ 6 months -80°C ≤ 4 F/T cycle

Aβ42/40 - The ratio of Aβ42 to Aβ40 is a biomarker of amyloid plaque accumulation in the brain. A lower Aβ42/40 is indicative of AD, as Aβ42 is more prone to aggregation plaques; normalization with Aβ40 helps ameliorate inter-individual differences in amyloid levels and increases diagnostic accuracy. The Lumipulse CSF Aβ42/40 is the first FDA-approved IVD for detection of AD amyloid pathology.

Neurocode is a clinical laboratory that offers world-class testing solutions for neurological disorders. We specialized in developing best-in-class high-complexity neurodegeneration and neuroimmunology assays. Neurocode is a joint venture between BC Neuroimmunology Labs (BCNI) and Avero Diagnostics. BCNI has served Canada with specialized neuroimmunology assays for four decades. Avero is a physician-owned clinical laboratory that offers a variety of clinical pathology and diagnostic testing options.

Neurocode's CAP-accredited (9838151) facility is located in Bellingham, WA under CLIA license 50D2301382.

Sample Shipping: Plasma samples should be refrigerated and shipped with ice packs for transport. CSF samples must be frozen and packaged with dry ice.

Ship Next-Day to:
ATTN: Neurocode
3548 Meridian St, Suite 101
Bellingham, WA 98225

References

1. 2022 Alzheimer's disease facts and figures. *Alzheimers Dement.* 2022 Apr;18(4):700-789. doi: 10.1002/alz.12638. Epub 2022 Mar 14. PMID: 35289055.
2. Hansson O, Edelmayer RM, Boxer AL, Carrillo MC, Mielke MM, Rabinovici GD, Salloway S, Sperling R, Zetterberg H, Teunissen CE. The Alzheimer's Association appropriate use recommendations for blood biomarkers in Alzheimer's disease. *Alzheimers Dement.* 2022 Dec;18(12):2669-2686. doi: 10.1002/alz.12756. Epub 2022 Jul 31. PMID: 35908251; PMCID: PMC10087669.