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 Aβ-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	Methodology	Intended Use
Plasma phosphorylated Tau 181 (p-tau181)	SIMOA	Clinical trial research
Plasma phosphorylated Tau 217 (ALZpath Dx pTau-217)	CLEIA / SIMOA	LDT for clinical use / clinical trial research
Plasma neurofilament light chain (Nf-L)	CLEIA / SIMOA	LDT for clinical use / clinical trial research
Plasma glial fibrillary acidic protein (GFAP)	SIMOA	Clinical trial research
CSF panel - total Tau, amyloidβ 42/40 (Aβ42/40), ptau-181, and Nf-L	CLEIA	IVD & LDTs for clinical use
APOE genotype	Mass Spec	LDT for clinical use

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

p-tau181 – Elevated levels of p-tau181 are associated with Aβ and tau pathologies in the brain and can be used to discriminate AD from non-AD dementias. Clinical performance was determined using plasma samples from autopsy-confirmed cases (N = 380).

AMR (ng/L)	AUC	Cut-off (ng/L)	Specificity	Sensitivity	Stability
6.17 - 300	0.91	46.1	89.4%	83.2%	1 week 4°C 3 weeks -20°C ≤ 5 F/T cycles

p-tau217 – Plasma p-tau217 levels correlate with tau-PET imaging and are more sensitive and specific than p-tau181 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	0.94	0.63	95.3%	95.8%	1 week 4°C 4 weeks -20°C ≤ 5 F/T cycles

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

AMR (ng/L)	Precision	Accuracy	Reference range (ng/L)	Stability
0.48 - 937.6	≤ 20% intra-laboratory	96.8%	≤ 120	≤ 72 hr 4°C 1 week -20°C ≤ 1 F/T cycle

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	≤ 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	≤ 4 hours 4°C 1 week -20°C ≤ 1 F/T cycle

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 (8446395) facility is housed within Avero's Bellingham, WA laboratory under CLIA license 50D2158817.

Sample Shipping: Plasma and CSF samples must be frozen and packaged with dry ice for transport. Ship Next-Day to: ATTN: Neurocode, 3548 Meridian St, Suite 100, Bellingham, WA 98225

Neuroimmunology Test Offerings

Test Name	Methodology	Intended Use
Acetylcholine receptor (AChR) antibodies	RIPA	LDT for clinical use
Acetylcholine receptor (AChR) antibodies	Live-CBA	LDT for clinical use
Muscle specific kinase (MuSK) antibodies	RIPA	LDT for clinical use
Low-density lipoprotein receptor-related protein 4 (LRP4) antibodies	CBA	Research testing
Voltage-gated calcium channel (VGCC) antibodies	RIPA	IVD for clinical use
Aquaporin-4 (AQP4) antibodies	Live-CBA	LDT for clinical use
Myelin oligodendrocyte (MOG) antibodies	Live-CBA	LDT for clinical use
Autoimmune encephalitis panel and paraneoplastic neurological syndrome panel	Panel	Research testing
Autoimmune nodopathy antibody screen (NF140, NF155, CNTN1, CASPR1)	CBA	LDT for clinical use

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.