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CSF Panel – Amyloid-Beta 42/40, Total Tau, Phosphorylated Tau 181, Neurofilament Light Chain

Test Name	CSF Panel – Amyloid-β, total tau, phosphorylated tau 181, neurofilament light chain
Abbreviation	CSF – tTau, pTau181, NfL
CPT code	83520 (x3)
Methodology	Chemiluminescent enzyme immunoassay (CLEIA)
Intended Use	The use of Lumipulse G β-Amyloid Ratio (1-42/1-40) for assessing the underlying AD-associated pathology in conjunction with clinical assessment to increase diagnostic certainty.
Test requirements	Specimen Type: CSF Minimum volume: 5 mL Preferred volume: 8 mL Rejection criteria: Sample arrives thawed; quantity not sufficient; gross hemolysis
Specimen collection	• Collect cerebral spinal fluid (CSF) directly into Sarstedt Liquor low protein binding tubes. Samples cannot be aliquoted from another tube into CSF tube. • If first 1mL collected is hemolyzed, discard and continue collection with a new Sarstedt tube. • Ship upright on cold packs
Specimen stability	Up to 48 hrs at room temp (15 - 25°C) Up to 8 days refrigerated (2 - 8°C) Up to 2 weeks at -20°C Up to 1 months at -70°C ≤ 1 freeze/thaw is acceptable. Do not freeze blood contaminated CSF for testing.
Test schedule	Once a week
TAT	1 – 3 days
Reference range	Positive ≤ 0.058 Likely positive 0.059 – 0.072 Negative ≥ 0.073
Limitations	• Not intended to be used as a stand-alone test; the test results must be interpreted in conjunction with other diagnostic tools and clinical information. • A positive result is associated with the presence of amyloid plaques or neurofibrillary tangles in the brain but does not establish a diagnosis of AD as would be established by neuropathological examination. • Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with immunoassays. People routinely exposed to animals or animal serum products or who have received mouse monoclonal antibodies for diagnosis or therapy can be prone to this interference. Such specimens may show either falsely elevated or falsely depressed values.

References	• Schneider JA, et al. The neuropathology of probable Alzheimer disease and mild cognitive impairment. Ann Neurol. 2009 Aug;66(2):200-8. • Gobom J, et al. Validation of the LUMIPULSE automated immunoassay for the measurement of core AD biomarkers in cerebrospinal fluid. CCLM. 2022 Jan 27;60(2):207-19. • Syrjanen JA, et al. Associations of amyloid and neurodegeneration plasma biomarkers with comorbidities. Alzheimer's & Dementia. 2022 Jun;18(6):1128-40. • O'Bryant SE, et al. Medical comorbidities and ethnicity impact plasma Alzheimer's disease biomarkers: important considerations for clinical trials and practice. Alzheimer's & Dementia. 2023 Jan;19(1):36-43.