Overview

Useful For
Quantitative measurement of phosphorylated Tau at threonine 181(pTau 181) in human cerebrospinal fluid

Method Name
Chemiluminescent Immunoassay

NY State Available
Yes

Reporting Name
Phospho-Tau 181, CSF

Aliases
p-Tau 181

Specimen

Specimen Type
CSF

Specimen Required
Container/Tube: Sarstedt Aliquot Tube, 5 mL 62.504.040
Specimen Volume: 1 mL
Collection Instructions:
1. Perform lumbar puncture and discard the first 1 to 2 mL of cerebrospinal fluid (CSF).
2. Collect CSF directly into one of the listed collection tubes
Note: Polypropylene collection tubes must be used. Polystyrene collection tubes are not acceptable.
3. Inspect specimen for visible blood contamination:
a. If bloody, centrifuge specimen and transfer supernatant to a new one of the listed collection tubes prior freezing and sending to laboratory. The supernatant, not the cellular material, is used for analysis.
b. If specimen is clear, centrifugation is not necessary.
4. Freeze sample upright prior to placing in transport container.

Specimen Minimum Volume
0.75 mL

Reject Due To

Gross hemolysis	Reject
Thawing	Cold OK; Warm reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
CSF	Frozen	90 days	

Clinical & Interpretive

Clinical Information
Two neuropathologic features observed in the brain of patients with Alzheimer disease dementia are the presence of plaques composed of beta-amyloid (Abeta) peptides and intracellular neurofibrillary tangles containing hyperphosphorylated Tau (tubulin-associated unit) proteins (pTau). These 2 groups of molecules are the most established biomarkers of the disease used in clinical and research practice. Measuring of certain pTau (such as pTau181) proteins in cerebrospinal fluid may be used to assess the presence of amyloid pathology.
The p-Tau181 assay used here has been reported to have an area under the receiver operating characteristic curve of 0.84 (95%CI 0.75–0.93) for detection for an abnormal amyloid-positron emission tomography as assessed by visual read. (1)

Reference Values
< or =63 pg/mL

Interpretation
A cutoff of 63 pg/mL has an 80% positive percent agreement, 83% negative percent agreement, and 81% overall percent agreement with amyloid-positron emission tomography (PET).(1)
A phosphorylated Tau181 concentration less than or equal to 63 pg/mL will be most consistent with a negative amyloid-PET.
A phosphorylated Tau181 concentration greater than 63 pg/mL will be most consistent with a positive amyloid- PET.

Cautions
Phosphorylated-Tau181 (pTau181) results must be interpreted in conjunction with other diagnostic tools, such as neurological examination, neurobehavioral tests, imaging, and routine laboratory tests.
In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.
Results obtained with different assay methods or kits may be different and cannot be used interchangeably.

Clinical Reference
1. Alcolea D, Pegueroles J, Munoz L, et al. Agreement of amyloid PET and CSF biomarkers for Alzheimer's disease on Lumipulse. Ann Clin Transl Neurol. 2019;6(9):1815-1824
2. Leitao MJ, Silva-Spinola A, Santana I, et al. Clinical validation of the Lumipulse G cerebrospinal fluid assays for routine diagnosis of Alzheimer's disease. Alzheimers Res Ther. 2019;11(1):91. Published 2019 Nov 23. doi:10.1186/s13195-019-0550-8
3. Gobom J, Parnetti L, Rosa-Neto P, et al. Validation of the LUMIPULSE automated immunoassay for the measurement of core AD biomarkers in cerebrospinal fluid. Clin Chem Lab Med. 2021;60(2):207-219. Published 2021 Nov 15. doi:10.1515/cclm-2021-0651
4. Campbell MR, Ashrafzadeh-Kian S, Petersen RC, et al. P-tau/Abeta42 and Abeta42/40 ratios in CSF are equally predictive of amyloid PET status. Alzheimer's Dement. 2021;13:e12190

Performance

Method Description
The Lumipulse G pTau 181 is an assay system for the quantitative measurement of phosphorylated Tau (pTau) 181 in cerebrospinal fluid specimens based on chemiluminescent immunoassay technology by a specific two-step sandwich immunoassay method on the Lumipulse G System. The specimen and biotinylated antibody solution are both added to the antibody coated particle solution. The pTau 181 in the specimen specifically binds to anti-pTau 181 monoclonal mouse antibody on the particles and biotinylated mouse antibody. Biotinylated antibody-antigen immunocomplexes are

formed. The particles are washed and rinsed to remove unbound materials. Alkaline phosphatase labeled streptavidin specifically binds to biotinylated immuno-complexes on the particles. The particles are washed and rinsed to remove unbound materials. Substrate solution is added and mixed with the particles. 3-(2'-Spiroadamantyl)-4-methoxy-4-(3"-phosphoryloxy)-phenyl-1,2-dioxetane (AMPPD) contained in the substrate solution is dephosphorylated by the catalysis of alkaline phosphatase indirectly conjugated to particles. Luminescence (at a maximum wavelength of 477 nm) is generated by the cleavage reaction of dephosphorylated AMPPD. The luminescent signal reflects the amount of pTau 181 present in the sample.(Package insert: Lumipulse G pTau 181. Fujirebio Inc; 03/2023)

Day(s) Performed
Tuesday. Days performed may be flexible if samples are scheduled to arrive in a batch.

Report Available
1 to 9 days

Specimen Retention Time
90 days

Performing Laboratory Location
Rochester

CLIA Laboratory Number
24D1040592

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.