# Mayo Clinic BioPharma Diagnostics

## Test Definition: B181P

Phosphorylated Tau 181, Plasma

## Overview

### Useful For

Quantitative measurement of phosphorylated Tau at threonine 181 in human plasma

### Highlights

BioPharma Diagnostics Use Only.

This assay is designed to specifically measure the phosphorylation of tau protein at position threonine 181 in human plasma.

### Method Name

Chemiluminescent Enzyme Immunoassay (CLEIA)

### NY State Available

Yes

### Reporting Name

Phospho-Tau 181, P

### Aliases

p-Tau 181
pTau181

## Specimen

### Specimen Type

Plasma

### Specimen Required

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube:** Lavender top (EDTA)
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 1 mL
**Collection Information:** Centrifuge and aliquot plasma into a plastic vial. **Do not** submit in original tube.

### Specimen Minimum Volume

0.5 mL

### Reject Due To

| | |
|---|---|
| Gross hemolysis | OK |
| Thawing | Cold, OK; Warm, Reject |
| Gross lipemia | OK |
| Gross icterus | OK |

### Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| EDTA Plasma | Frozen (preferred) | 90 days | |
| | Ambient | 24 hours | |
| | Refrigerated | 72 hours | |

## Clinical & Interpretive

### Clinical Information
In Alzheimer disease (AD), phosphorylation of Tau (tubulin-associated unit) protein is altered, leading to hyperphosphorylation (pTau) at various sites. Phosphorylation of Tau at position 181 has been shown to correlate with the presence of amyloid pathology in individuals with AD.

Current research indicates that plasma pTau, including pTau181, is concordant with amyloid-positron emission tomography, and can differentiate between AD and non-AD neurodegenerative diseases and predict progression to AD. Blood-based biomarkers, such as plasma pTau181, could potentially be used in clinical trials as inclusion criteria or to evaluate target engagement and treatment efficacy, and could further advance the development of disease-modifying treatments in the field of AD and related disorders.

### Reference Values
< or = 2.5 pg/mL

### Interpretation
A phosphorylated Tau181 (pTau181) concentration less than or equal to 2.5 pg/mL is suggestive of a negative amyloid-positron emission tomography (PET).

A pTau181 concentration greater than 2.5 pg/mL is suggestive of 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.

The safety and effectiveness of this test have not been established for monitoring the effect of any therapeutic product or for predicting development of dementia or other neurologic conditions.

Results obtained with different assay methods or kits may be different and cannot be used interchangeably.
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) that 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.

### Clinical Reference
1. Figdore DJ, Wiste HJ, Bornhorst JA, et al. Performance of the Lumipulse plasma Aß42/40 and pTau181 immunoassays in the detection of amyloid pathology. Alzheimers Dement (Amst). 2024;16(1):e12545. Published 2024 Jan 31. doi:10.1002/dad2.12545

## Performance

### Method Description
The Lumipulse G pTau 181 is an assay system for the quantitative measurement of phosphorylated Tau (pTau) 181 in plasma 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, forming biotinylated antibody- antigen immunocomplexes. 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 Plasma. Fujirebio Inc; 02/2022)

### Day(s) Performed
Tuesday. Testing may be performed on additional days per client request.

### Report Available
1 to 7 days

### Specimen Retention Time
3 months

### Performing Laboratory Location
Rochester

### CLIA Laboratory Number
24D1040592

### Test Classification
This test was developed and its performance characteristics were 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.