

# Phospho-Tau 217, Plasma

Test ID: PT217

## Useful for:

Evaluation of individuals, aged 50 years and older, presenting with cognitive impairment who are being assessed for Alzheimer disease and other causes of cognitive decline.

This test is not intended as a screening test for Alzheimer disease in asymptomatic individuals.

### Methods:

Chemiluminescent Enzyme Immunoassay

### **Reference Values:**

Negative < or = 0.185 pg/mL Intermediate 0.186-0.324 pg/mL Positive > or = 0.325 pg/mL

## **Specimen Requirements:**

| Collection Container/Tube:      | Lavender top (EDTA)   |
|---------------------------------|---|
| Submission Container/Tube:      | Plastic screw-top vial  |
| Specimen Volume:                | 0.6 mL  |
| <b>Collection Instructions:</b> | Centrifuge and aliquot plasma into plastic vial. Do <b>not</b> submit in original tube. |
| Minimum Volume:                 | 0.5 mL  |

### **Specimen Stability Information:**

| Specimen Type | Temperature              | Time     |
|---------------|--------------------------|----------|
| EDTA Plasma   | Refrigerated (preferred) | 7 days   |
|               | Ambient                  | 72 hours |
|               | Frozen                   | 7 days   |

## **Cautions:**

Phosphorylated Tau217 (p-Tau217) results must be interpreted in conjunction with other diagnostic tools, such as neurological examination, neurobehavioral tests, imaging, and routine laboratory tests.

This assay should not be ordered for individuals younger than 50 years.

Elevations of p-Tau217 may be seen in individuals with impaired kidney function associated with chronic kidney disease and should be interpreted with caution in these situations.

False-positive or false-negative test results may occur.

The performance of this test was evaluated using specimens obtained from a US White population. At this time, it is uncertain if similar clinical performance will be observed in other racial and ethnic groups.

This assay should not be used for cognitively unimpaired (asymptomatic) individuals to predict the development of dementia or other neurological conditions.

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

p-Tau217 concentrations have not been established to correlate with disease severity.

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 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.

**CPT Code:** 83520

Day(s) Performed: Tuesday, Thursday

Report Available: 1 to 5 days

#### Questions

Contact Bethany Feind, Laboratory Resource Coordinator at 800-533-1710.