Phospho-Tau 217, Plasma

Last Literature Review: March 2025 Last Update: April 2025

The phosphorylated tau 217 (pTau 217) test is used to evaluate for Alzheimer's disease (AD) and other causes of cognitive impairment in adults 60 years and older who present with cognitive decline. This is not a standalone test; it should be used as part of a comprehensive diagnostic workup.

This test uses a chemiluminescent immunoassay to measure the concentration of pTau 217 in plasma. This concentration is used to determine a qualitative result (positive, negative, or indeterminate), which is reported.

Featured ARUP Testing

Phospho-Tau 217, Plasma 3019017

Method: Qualitative Chemiluminescent Immunoassay (CLIA)

Disease Overview

AD is a neurodegenerative disorder characterized by progressive memory loss and eventual dementia.[1,2] AD is primarily diagnosed through clinical examination, which may be supported by amyloid positron emission tomography (PET) imaging and laboratory testing.[1,2,3,4]

Several fluid biomarker tests have demonstrated sufficient accuracy for use in the diagnosis of AD. These biomarkers reflect early beta (β)-amyloid and/or tau pathophysiologic processes and are considered "core" biomarkers of AD.

Accurate plasma pTau 217 assays can be diagnostic of AD. The Alzheimer's Association defines an accurate test as one with an "accuracy equivalent to that of approved CSF [cerebrospinal fluid] assays" (approximately 90%) in detecting abnormal amyloid PET imaging results in the intended use population.[5] Results of this assay correlate highly with the presence or absence of amyloid deposition as measured by an amyloid PET scan. In a clinical validation set of 524 participants 60 years and older who presented with cognitive impairment, a positive result had a sensitivity of 90%, a negative result had a specificity of 90%, and 17% of the results were indeterminate. Receiver operating characteristic (ROC) curve analysis demonstrated high diagnostic accuracy, with an area under the curve (AUC) of 0.941 (94.1%).

Test Interpretation

Kit Used

Human p-Tau217 Planar Kit

Summary of Clinical Performance

Two quantitative cut points were determined to define qualitative outputs (positive, indeterminate, or negative), which are to be used for diagnostic interpretation. The cut points were chosen to optimize clinical sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), while reducing the indeterminate rate. Refer to the table below for a summary of clinical performance.

Summary of Clinical Performance

Metric	Percent (%)
Prevalence (PET positive)	64.9
Sensitivity	90
Specificity	90
PPV	94
NPV	84
Indeterminate rate	17
AUC	94.1

Results Interpretation

The report will provide a qualitative result (positive, negative, or indeterminate). The quantitative value used to determine the qualitative result will be included in the Interpretative Data section. Refer to the following table for more information on quantitative cut points and the associated clinical interpretations.

Results and Interpretive Information for pTau 217, Plasma		
pTau 217 Result	**Value**	**Interpretive Information**
Negative	<0.13 U/mL	A test result reported as negative is consistent with the absence of amyloid deposition in the brain as detected by an amyloid PET scan A negative result reduces the likelihood that a patient's cognitive impairment is due to AD
Indeterminate	≥0.13 to <0.20 U/mL	A test result reported as indeterminate indicates that amyloid plaques may or may not be present Additional diagnostic testing, such as other laboratory testing or an amyloid PET scan, should be considered based on clinical presentation If symptoms persist or evolve, repeat testing may be helpful
Positive	≥0.20 U/mL	A test result reported as positive is consistent with the presence of amyloid deposition in the brain as measured by an amyloid PET scan A positive result alone does not establish a diagnosis of AD or another cognitive disorder

Limitations

- The results of the plasma pTau 217 test must be interpreted in conjunction with other patient-specific clinical information. The test is not intended to be used as a screening or standalone diagnostic test and is not intended for therapeutic monitoring.
- Results obtained with different assay methods or kits cannot be used interchangeably.

References

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3. Hansson O, Seibyl J, Stomrud E, et al. CSF biomarkers of Alzheimer's disease concord with amyloid-β PET and predict clinical progression: a study of fully automated immunoassays in BioFINDER and ADNI cohorts. *Alzheimers Dement*. 2018;14(11):1470-1481.

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5. Jack CR Jr, Andrews JS, Beach TG, et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. *Alzheimers Dement*. Published Jun 2024; accessed Aug 2024.

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