LucentAD p-Tau 217

Turnaround Time

10 days

- Turnaround time is defined as the usual number of days from the date of sample receipt to when the result is released to the ordering provider. In some cases, increased time should be allowed for additional confirmatory or reflex tests. Testing schedules may vary.

Related Documents

For more information, please view the literature below:

- LucentAD: A Guide for Providers
- LucentAD Test Report
- Alzheimer's Detection Made Simple Whitepaper

Sample Requirements

Requirements	
Specimen	K2 EDTA Plasma
Volume	1 mL
Minimum Volume	0.5 mL
Collection Container	Pearl-top tube, gel-barrier tube
Transport Container	Pearl-top tube, gel-barrier tube
Storage Instructions	Refrigerated

Sample Stability Requirements

Temperature	Period
Refrigerated	7 Days
Frozen	14 Days
Ambient	8 hours
Freezer/Thaw Cycles	Stable x3

Test Details

Use

- Lucent AD is used for the measurement of phosphorylated Tau 217 (p-Tau 217) in human plasma. p-Tau 217 is associated with amyloid pathology, a hallmark of Alzheimer's disease.

Limitations

- This test was developed, and its performance characteristics determined by Quanterix. It has not been cleared or approved by the US Food and Drug Administration.
- There are significant variations in measured plasma p-Tau 217 levels among different methods and labs. Care must be taken when interpreting results obtained in different studies.
- LucentAD test results should only be used in conjunction with other clinical information when evaluating patients.

Interpretations

- The LucentAD p-Tau 217 test is intended to be used in patients who are being evaluated for Alzheimer's disease (AD) to aid in diagnostic evaluation. A low result by the LucentAD p-Tau 217 test at or below 0.040 pg/mL indicates a low likelihood of the presence of amyloid pathology. Alternative causes for the patient's memory concerns should be investigated. An elevated result at or above 0.090 pg/mL indicates a high likelihood of the presence of amyloid pathology. An elevated result at or above 0.090 pg/mL is consistent with the presence of Alzheimer's disease but does not in itself establish a diagnosis. Test results in the diagnostic gray zone from 0.041 and 0.089 pg/mL, are associated with an intermediate likelihood of amyloid pathology. If clinically indicated, an intermediate result may require referral for evaluation by other methods such as CSF biomarker testing or PET imaging to confirm the absence or presence of amyloid pathology. See the cutoff table below.

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p-Tau 217 (pg/mL)	Result Comment
≤ 0.040	Low likelihood of amyloid pathology
0.041 – 0.089	Intermediate likelihood of amyloid pathology If clinically indicated, consider confirmatory testing
≥ 0.090	High likelihood of amyloid pathology

Test Details (Cont.)

Test Information

- The LucentAD test helps identify whether a patient with concerns about memory and/or thinking ability is likely or unlikely to have amyloid plaques in the brain, a hallmark of Alzheimer's disease. The LucentAD p-Tau 217 test measures tau protein phosphorylated at threonine 217. Circulating levels of p-Tau 217 have been shown to be a biomarker strongly associated with amyloid plaque pathology.1,2 LucentAD p-Tau 217 is not a standalone diagnostic test. LucentAD results support a diagnostic assessment as an adjunct to other methods, such as clinical assessment, exclusionary blood workup, and cognitive evaluations. In uncertain cases, including an intermediate result from the LucentAD p-Tau 217 test, cerebrospinal fluid (CSF) biomarker tests or amyloid positron emission tomography (PET) may be indicated for further evaluation of amyloid pathology status to support a diagnosis.
  The LucentAD p-Tau 217 test is intended to assess the likelihood of the presence of amyloid pathology in patients with mild cognitive impairment and early Alzheimer's disease. The assay was validated with 873 subjects with known baseline amyloid beta status by CSF biomarkers or amyloid PET testing. Diagnostic categories ranged from mild cognitive impairment to Alzheimer's dementia. At or below a negative cutoff of 0.040 pg/mL, the LucentAD p-Tau 217 test demonstrated a sensitivity of 90.3%.* At or above a positive cutoff of 0.090 pg/mL, the test demonstrated a specificity of 91.3%.* The overall test accuracy, defined as the ratio of correct results divided by the sum of correct results plus incorrect results as compared CSF biomarker test was 90.7%. Values from 0.041 and 0.089 pg/mL have increased uncertainty regarding amyloid pathology status. 30.9% of the validation samples gave results in the intermediate range.

*Excluding samples in the intermediate range.

1. Therriault J, Vermeiren M, Servaes S, et al. Association of Phosphorylated Tau Biomarkers With Amyloid Positron Emission Tomography vs Tau Positron Emission Tomography. JAMA Neurol. 2023;80(2):188-199.
2. Doré V, Doecke JD, Saad ZS, et al. Plasma p217+tau versus NAV4694 amyloid and MK6240 tau PET across the Alzheimer's continuum. Alzheimer's Dement (Amst). 2022;14(1):e12307. Published 2022 Apr 5.

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Method Description

- p-Tau 217 is measured on the Quanterix Simoa HD-X analyzer using the Simoa p-Tau assay. The assay uses two Tau specific monoclonal antibodies. Anti-p-Tau 217 antibody coated paramagnetic beads are combined and incubated with sample alone. The p-Tau 217 antigen present in the sample is captured by the antibody coated beads. After washing, anti-p-Tau 217 biotinylated detector antibodies are mixed and incubated with the beads. The detector antibodies bind to the captured p-Tau 217 during this additional incubation.

  Following a washing step, a conjugate of streptavidin-beta-galactosidase (SBG) is mixed with the capture beads. The captured p-Tau 217 becomes enzymatically labeled when the SBG binds to the biotinylated detector antibodies. During the final wash step, the beads are resuspended in a resorufin beta-D- galactopyranoside (RGP) substrate solution. This suspension is transferred to the Simoa Disc. Individual paramagnetic capture beads settle into 216,000 femtoliter-sized microwells designed to hold no more than one bead per well. The beads are sealed into the microwells while excess beads are washed away with a synthetic fluorinated polymer sealing oil.

  If p-Tau 217 is present in the sample and subsequently captured and labeled, the beta-galactosidase hydrolyzes the RGP substrate and produces a fluorescent signal. This signal is detected and counted by the Simoa optical system. The concentration of p-Tau 217 is interpolated from a standard curve.

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