Lucent Diagnostics

LucentAD

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

Stability Requirements

Temperature	Period
Refrigerated	7 Days
Frozen	7 Days
Freezer/Thaw Cycles	Stable x3

Test Details

Use

- Lucent AD is used for the measurement of phosphorylated Tau 181 (p-Tau181) in human plasma. p-Tau 181 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 181 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 test is intended for patients who are being evaluated for Alzheimer's disease risk to aid in diagnostic evaluation. A negative result by the LucentAD test (below the cutoff) indicates a low likelihood of the presence of amyloid pathology and that alternative causes for the patient's memory concerns should be investigated. A positive result by the LucentAD test (above the cutoff) is consistent with the presence of amyloid pathology and that additional confirmatory testing may be indicated for a diagnosis. See the cutoff table below.

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p-Tau181 (pg/mL)	Test Result	Interpretation
<14.2	Negative	Unlikely amyloid pathology
≥14.2	Positive	Possible 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 test measures tau protein phosphorylated at threonine 181 (p-Tau 181). Circulating levels of p-Tau 181 have been shown to be a biomarker strongly associated with amyloid plaque pathology.[1,2] LucentAD is not a standalone diagnostic test. LucentAD results support a diagnostic assessment as an adjunct to other methods, such as an initial exclusionary blood workup, cognitive evaluations, CSF biomarker tests, and amyloid positron emission tomography (PET).
- The LucentAD test was optimized to maximize the clinical sensitivity and negative predictive value. To validate the cutoff, the test was performed on 293 patients from different clinical sites who were diagnosed with mild cognitive impairment based on clinical and cognitive assessments.[3] At a cutoff of 14.2 pg/mL, the LucentAD test demonstrated a clinical sensitivity of 90% and a specificity of 56%. The prevalence of amyloid positivity in this cohort was 34.5%. At this prevalence, the negative predictive value of the test was determined to be 91.4%.

1. Karikari, T., et. al. Molecular Psychiatry (2021) 26:429–442. https://doi.org/10.1038/s41380-020-00923-z.
2. Karikari, T. et. al. The Lancet Neurology (2020), 19:422-433. https://doi.org/10.1016/S1474-4422(20)30071-5.
3. Global Alzheimer's Platform Foundation Biohermes Study https://globalalzplatform.org/biohermesstudy/ June 2023

Method Description

- p-Tau 181 is measured on the Quanterix Simoa HD-X analyzer using the Simoa p-Tau 181 advantage kit. The assay uses two Tau specific monoclonal antibodies. Sample, paramagnetic capture beads coated with anti-p-Tau 181 antibody, and a biotinylated detector antibody are combined. Anti-p-Tau 181 antibody coated paramagnetic capture beads and labeled biotinylated detector antibody will bind to phosphorylated Tau 181 molecules present in the sample. Following a washing step, a conjugate of streptavi- din-beta-galactosidase (SBG) is mixed with the capture beads. The captured p-Tau 181 becomes enzymatically labeled when the SBG binds to the biotinylated detector antibodies. A second wash is performed, and the capture 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 181 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 181 is interpolated from a standard curve.

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