Patient Name		
Sex	Age	Date of Birth DD-MMM-YYYY
Sample Number		Sample Type ☐ K2EDTA Plasma
Provider Name		Collection Date DD-MMM-YYYY
Organization		Collection Time HH:MM
Secure Fax#:		Date Received DD-MMM-YYYY
		Report Date DD-MMM-YYYY

104142 LucentAD p-Tau 181 Test, Plasma

Result (pg/mL)

XX.XX

Interpretation: The LucentAD test is intended to be used in patients who are being evaluated for Alzheimer's disease risk to aid in diagnostic evaluation. For a negative result by the LucentAD test (below the cutoff), the high negative predicted value (NPV) of the test 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 a higher likelihood of the presence of amyloid pathology and that additional confirmatory testing may be indicated for a diagnosis.

p-Tau 181 (pg/mL)	Test Result	Interpretation
<14.2	Negative	Unlikely amyloid pathology
≥14.2	Positive	Possible amyloid pathology

As with any quantitative test, there is statistical uncertainty at or near a cutoff. Retesting of samples with results at or near the cutoff may be advisable.

Quanterix Laboratory Director: Timothy Skelton, M.D., Ph.D., ABPD

Test Information: The LucentAD p-Tau 181 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 p-Tau 181 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 for patients with MCI and early Alzheimer's pathology as confirmed by amyloid PET. To validate the cutoff, the test was performed on 293 patients from different clinical sites who were diagnosed with MCI based on clinical and cognitive assessments.[3] The ability of the LucentAD test to identify patients with amyloid pathology in this cohort of mildly impaired individuals was determined. 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%.

This test was developed, and its performance characteristics determined by Quanterix Corporation in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

REFERENCES

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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