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| --- | --- | --- |
| Patient Name | | Unique ID |
| Sex | Age | Date of Birth DD-MMM-YYYY |
| Sample Number | | Sample Type ☐ K2 EDTA 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 |

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| --- | --- | --- |
| **105502 LucentAD Complete, Plasma** | | |
| **Result (0-100)** | **Result Comment** | |
| **XX** | **Risk Score Range** | **Test Result**  **Interpretation** |
| XX | XXX |
| **Comment:** | | |
| **Interpretation:** The LucentAD Complete Test is intended to be used in patients with cognitive symptoms who are being evaluated for Alzheimer’s disease (AD) to aid in diagnostic evaluation.  **Low:** A risk score below 45 by the AD Complete Test indicates a low likelihood of the presence of amyloid pathology. Alternative causes for the patient’s memory concerns should be investigated.  **Intermediate:** Test results in the intermediate risk range between 45 and 70 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.  **High:** A risk score above 70 indicates a high likelihood of the presence of amyloid pathology. An elevated risk score above 70 is consistent with the presence of amyloid pathology, a hallmark of Alzheimer’s disease, but does not in itself establish a diagnosis. | | |
| **Quanterix Laboratory Director: Timothy Skelton, M.D., Ph.D., ABPD** | | |
| **Test Information:**  LucentAD Complete helps identify whether a patient with cognitive or memory concerns is likely or unlikely to have amyloid plaques in the brain, a hallmark of Alzheimer’s disease. LucentAD Complete measures five proteins associated with AD: phosphorylated tau 217 (p-Tau 217), amyloid beta 1-40 (Ab40), amyloid beta 1-42 (Ab42), glial fibrillary acidic protein (GFAP), and neurofilament light chain (Nf-L).1 These measurements are combined in an algorithm which generates a risk score designed to maximize accuracy and minimize uncertainty. LucentAD Complete is not a standalone diagnostic test. LucentAD Complete 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 LucentAD Complete test, cerebrospinal fluid (CSF) biomarker tests or amyloid PET may be indicated for further evaluation of amyloid pathology status to support a diagnosis.  LucentAD Complete is intended to assess the likelihood of the presence of amyloid pathology in patients with mild cognitive impairment and early AD. Assay cutoffs were established with a randomized sampling of 730 subjects with known amyloid status from two independent cohorts. The cutoffs were validated with a randomized sampling of 459 additional subjects from the two cohorts. The prevalence of amyloid positivity in this sampling was 58.2%. A negative result (risk score <45) would be consistent with absence of amyloid by PET/CSF and reduces the likelihood of cognitive impairment due to AD. A positive result (risk score >70) would be consistent with presence of amyloid by PET/CSF with a PPV of 92.5%. A positive result does not establish a diagnosis of AD or other cognitive disorders. A test result in the intermediate range (45-70) has increased uncertainty in regard to amyloid status by PET/CSF. 11.4% of the validation samples gave results in the intermediate range. The change of biomarker levels over time has not been established.  *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**   1. Pais MV, Forlenza OV, Diniz BS. Plasma Biomarkers of Alzheimer's Disease: A Review of Available Assays, Recent Developments, and Implications for Clinical Practice. J Alzheimers Dis Rep. 2023 May 3;7(1):355-380. | | |