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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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| --- | --- | --- |
| **104620 LucentAD p-Tau 217 Test, Plasma** | | |
| **Result (pg/mL)** | **Result Comment** | |
| **XX.XXX** pg/mL | **Range (pg/mL)** | **Result Comment** |
|  |  |
| **Comment:** | | |
| **Interpretation**  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. | | |
| **Quanterix Laboratory Director: Timothy Skelton, M.D., Ph.D., ABPD** | | |
| **Test Information**  The LucentAD p-Tau 217 test helps identify whether a patient with cognitive or memory symptoms 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 in regard to amyloid pathology status. 30.9% of the validation samples gave results in the intermediate range.  *\*Excluding samples in the intermediate range.*  *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. 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. | | |