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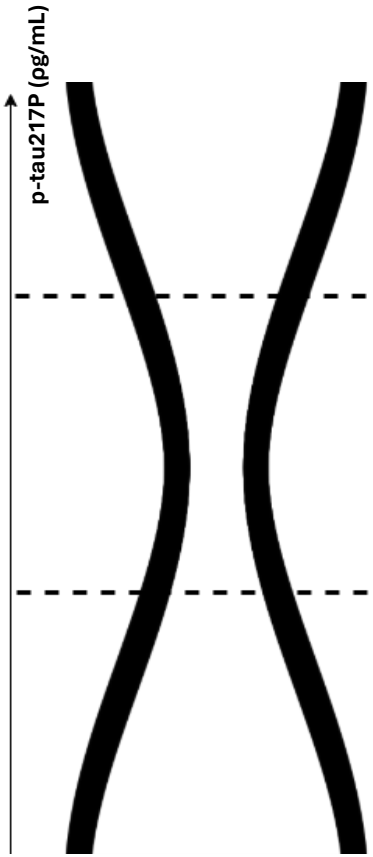
EDTA Plasma p-tau217P quantification (CLEA) - interpretation & contextualisation



p-tau217P	Concl. short	Conclusion	Extra + confounding factors
X ≥0.383 pg/mL **Cutoff high**	High AD-probability	Markedly elevated; Plasma p-tau217P concentration **indicates a high probability assessment of Alzheimer's disease pathology**. However, these findings do not exclude the presence of other underlying or concomitant pathologies.	This test should only be used in patients with an objective cognitive deficit and clinical suspicion of Alzheimer's disease; Analysis is designated RUO pending CE-IVD. **It may serve as an early, less-invasive probability assessment tool indicating initial pathological changes**, which should be confirmed by the standard CSF-based ATN profile; **Result can be affected by kidney function and BMI.**
X>0.158 pg/mL **X<0.383** pg/mL	Inconclusive AD-probability	Within an intermediate range; Plasma p-tau217P concentration **indicates an inconclusive probability assessment for Alzheimer's disease pathology**. Further **evaluation with CSF AD biomarkers** or Amyloid PET imaging is recommended. These findings do not exclude the presence of other underlying or concomitant pathologies.	This test should only be used in patients with an objective cognitive deficit and clinical suspicion of Alzheimer's disease; Analysis is designated RUO pending CE-IVD. It may serve as an early, less-invasive probability assessment tool indicating initial pathological changes, which should be confirmed by the standard CSF-based ATN profile; **Result can be affected by kidney function and BMI.**
Cutoff low **X ≤0.158** pg/mL	Low AD-probability	Within a low range; Plasma p-tau217P concentration **indicates a low probability assessment of Alzheimer's disease pathology**. However, these findings do not exclude the presence of other underlying or concomitant pathologies.	**This test should only be used in patients with an objective cognitive deficit and clinical suspicion of Alzheimer's disease**; Analysis is designated RUO pending CE-IVD. It may serve as an early, less-invasive probability assessment tool indicating initial pathological changes, which should be confirmed by the standard CSF-based ATN profile; **Result can be affected by kidney function and BMI.**

comments & references:	By **using a two cutoff approach**, with only the subgroup with inconclusive plasma p-tau217P results requiring confirmatory testing, the number of false positives and false negatives is reduced in comparison with a one cutoff approach. (*Brum et al. Nat Aging 2023; Hazan et al. Alzheimers Dement. 2025)* **Kidney function and BMI can potentially affect the test interpretation of plasma markers.** Although the impact of those factors seems rather modest, caution for interpretation is needed. *(Mielke et al. Nat Med. 2022; Pichet Binette et al. Alzheimers Dement. 2023; Arranz et al. Alzheimers Res Ther. 2024)*