

# Evaluation of a novel immunoassay to detect p-tau Thr127 in the CSF to distinguish Alzheimer disease from other dementias

Jozef Hanes, PhD, Andrej Kovac, PhD, Hlin Kvartsberg, PhD, et al.

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## Correspondence

Dr. Zilka  
zilka@axon-neuroscience.eu

## Study question

Do CSF levels of T217-phosphorylated tau (p-tau T217) provide a basis for differentiating patients with Alzheimer disease (AD) from healthy controls (HCs) and patients with other dementias?

## What is known and what this paper adds

The 3 major biomarkers for AD pathology are neurodegeneration, amyloid- $\beta$  accumulation, and tau protein pathology, and p-tau T217 is a recently reported additional biomarker. This investigation provides Class III evidence that a CSF immunoassay for p-tau T217 distinguishes AD from other dementias and HCs.

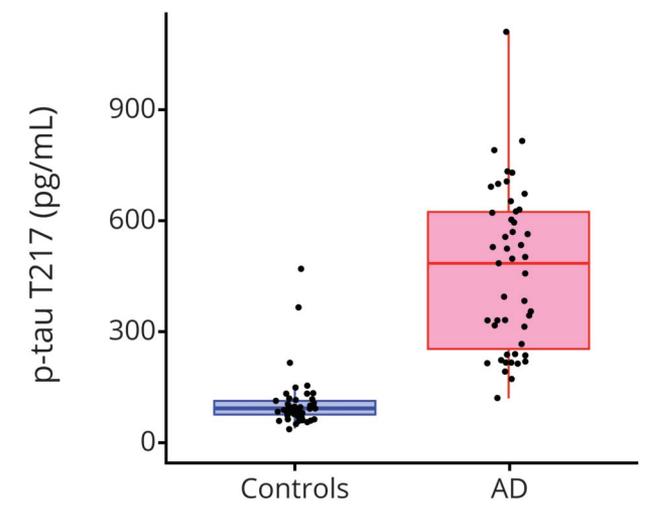
## Methods

For this diagnostic test study, the investigators analyzed CSF samples from 77 patients with AD, 44 HCs, and 69 patients with other neurodegenerative disorders, such as primary progressive aphasia, behavioral-variant frontotemporal dementia, progressive supranuclear palsy, and corticobasal degeneration. These individuals came from 3 cohorts recruited through academic centers in the Netherlands, Sweden, and Czechia. Clinicians had made diagnoses based on standard criteria. The investigators used a highly sensitive single-molecule array system to quantify CSF p-tau T217 levels. The investigators used receiver operating characteristic analyses to assess the diagnostic utilities of p-tau T217 levels. The primary outcomes were the sensitivities and specificities of the optimal p-tau T217 cut-off values for differentiating patients with AD from the HCs and patients with other disorders.

## Results and study limitations

A cut-off p-tau T217 level of 242 pg/mL differentiated patients with AD from patients with other neurodegenerative disorders, with 93% sensitivity (95% confidence interval [CI],

**Figure** CSF levels of p-tau T217 in the AD and HC groups



78%–99%) and 88% specificity (95% CI, 79%–98%), and a cut-off p-tau T217 level of 163 pg/mL differentiated patients with AD from HCs with 98% sensitivity (95% CI, 88%–99%) and 93% specificity (95% CI, 85%–99%). These findings are Class III evidence for the diagnostic utility of CSF p-tau T217 levels. The present study's limitations include small sample sizes and reliance on data from Europe, which may limit generalizability to non-European populations.

## Study funding and competing interests

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