Title: Clinical Implementation Of Plasma P-tau217 Testing For Alzheimer's Disease A Canadian Experience With Over 900 Tests

Pankaj Kumar[1,2], Ali Mousavi[1,2], Mary Encarnacion[2], YiLiang Zhang[2], Ryan Conkling[2], Brandon Krezeski[2], Waad Alshammari[1], Hans Frykman [1-3]

1. Department of Medicine, University of British Columbia, Vancouver, BC, Canada 2. BC Neuroimmunology lab, Vancouver, BC, Canada
3. Neurocode USA, Bellingham, WA, USA

Poster #10676

Background

Plasma p-tau217 is a robust biomarker for the diagnosis of Alzheimer's disease (AD), and we demonstrated its superior clinical performance in identifying AD in several studies. We present a series of plasma p-tau217 measurements used for the diagnosis of AD in a Canadian diagnostic laboratory.

Methods

Between May 2024 and December 2025

EDTA plasma Tested for plasma p-tau217 at BC Neuroimmunology lab, Vancouver, BC, Canada (n = 923)

Plasma p-tau217 levels were measured using two platforms which has been comprehensively validated in our labs

The ALZpath assay on the Quanterix HD-X Simoa platform (n=812)

The Lumipulse platform (n=111)

Results

ALZPath

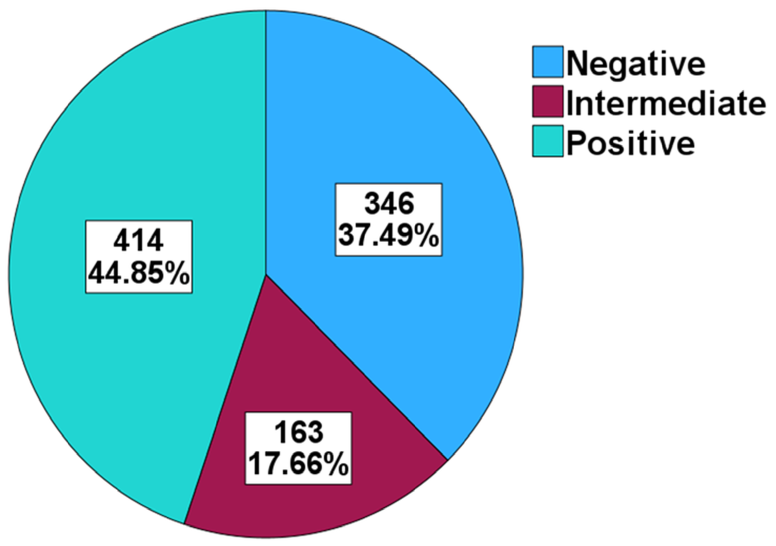
Negative	Intermediate	Positive
≤0.34 pg/L	0.35 -0.62 pg/L	≥ 0.63

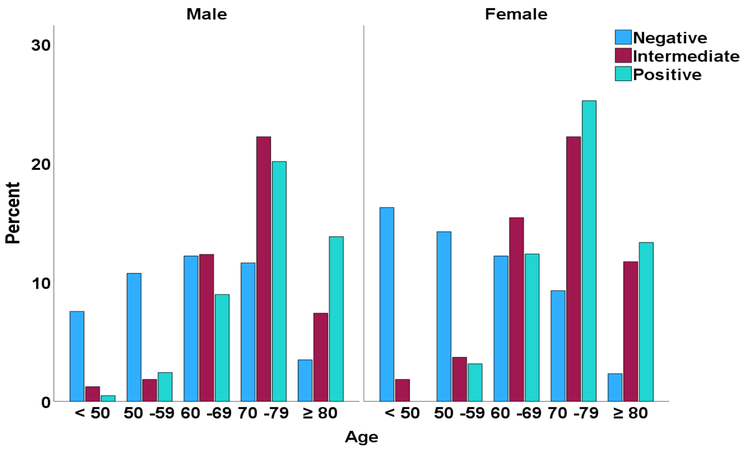
Matrix	Threshold	Specificity	Sensitivity	PPV	NPV
CSF (Aβ 42/40)	0.34 (Low)	90.0%	93.4%	93.9%	90.0%
	0.63 (High)	95.0%	72.7%	96.0%	67.9%
CSF (p-tau181)	0.34 (Low)	75.0%	93.1%	81.8%	90.0%
	0.63 (High)	87.5%	75.9%	88.0%	75.0%
Autopsy confirmed	0.34 (Low)	67.4%	95.8%	83.1%	90.6%
	0.63 (High)	95.3%	79.2%	96.6%	73.2%

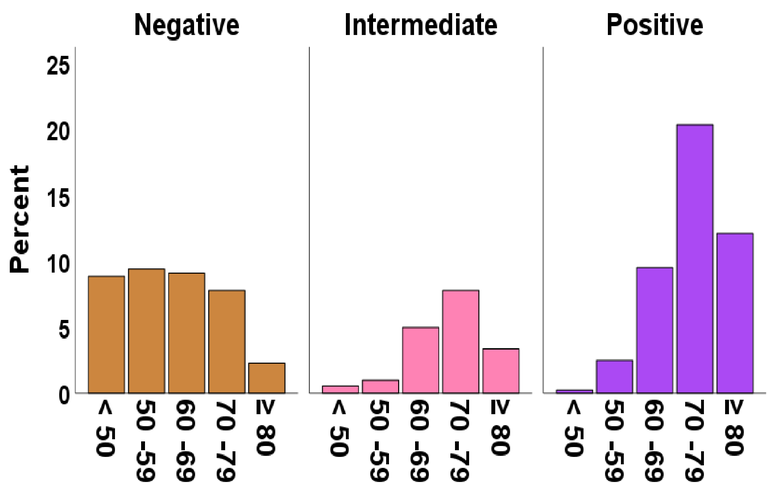
Lumipulse

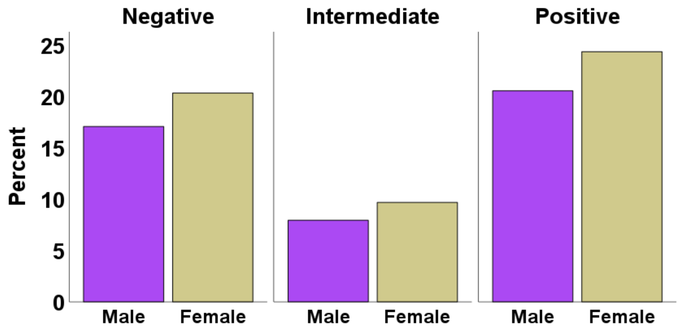
Negative	Intermediate	Positive
≤0.13 pg/L	0.14 -0.36 pg/L	≥ 0.37

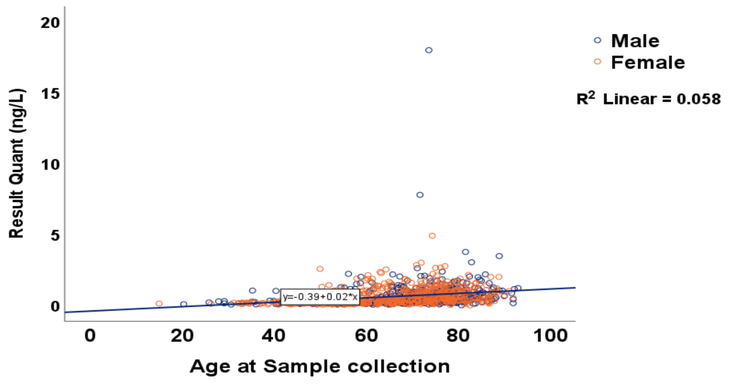
Matrix	Threshold	Specificity	Sensitivity	PPV	NPV
CSF (Aβ 42/40)	0.13 (Low)	84.2%	87.5%	90.3%	80.0%
	0.37 (High)	94.7%	59.4%	95.0%	58.1%
CSF (p-tau181)	0.13 (Low)	82.6%	96.4%	87.1%	95.0%
	0.37 (High)	95.7%	67.9%	95.0%	71.0%
Autopsy confirmed	0.13 (Low)	46.5%	96.6%	71.3%	90.9%
	0.37 (High)	93.0%	67.8%	93.0%	67.8%











Conclusion

These findings support the clinical utility of plasma p-tau217 assays in AD diagnosis but a statistically significant association between age and test results, independent of sex, supporting the need for age-specific interpretive frameworks in clinical practice.

References

Mammel AE, Hsiung GYR, Mousavi A, et al. Title: Alzheimer's disease clinical decision points for two plasma p-tau217 laboratory developed tests in neuropathology confirmed samples Abbreviated. doi:10.1101/2024.07.27.24310872

Acknowledgment

We thank our referring physicians for their trust and partnership in patient care.