March 23, 2026

Sysmex Corporation

【Overview presentation】

International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders: AD/PD™ 2026

Development of a fully automated plasma p-Tau205 immunoassay demonstrating high concordance with an immunoprecipitation mass spectrometry assay

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Overview presentation	**Objectives** Plasma biomarkers for Alzheimer's disease (AD) are increasingly recognized for their potential in patient classification. Phosphorylated tau (p-tau) species, characterized by distinct phosphorylation sites, are particularly promising, as their concentrations vary across the AD continuum. Among these, p-tau205 measured by immunoprecipitation-mass spectrometry (IP-MS) assay, which has high specificity to the target molecules, has shown the association with tau pathology. In this study, we developed a highly specific plasma p-tau205 immunoassay, which shows high concordance with the IP-MS assay. **Methods** We developed a plasma p-tau205 immunoassay using the Automated Immunoassay System HISCL™-5000. As a reference, an IP-MS assay was established based on previously reported protocols. To assess the specificity of our immunoassay, the correlation of p-tau205 levels between the two methods was evaluated. We measured plasma levels of p-tau205 using commercially available samples, including clinically diagnosed cognitively normal (CN, n=3), mild cognitive impairment (n=13) and AD (n=12). Furthermore, to evaluate disease-stage dependency, additional plasma p-tau205 samples with CN (n=10)

	and AD (n=9) were measured and their levels were compared using the Mann–Whitney U test. **Results** Plasma p-tau205 levels measured by both methods showed a significant correlation with Spearman's rank correlation coefficient of 0.84 ($p<0.001$). Plasma p-tau205 levels measured by HISCL-5000 were significantly higher in the AD group than in the CN group ($p<0.001$). **Conclusion** In this study, we developed a fully automated and highly specific plasma p-tau205 immunoassay that showed strong correlation with the IP-MS method, enabling reliable quantification directly from plasma. Plasma p-tau205 levels showed a significant elevation in the AD group, suggesting that our immunoassay may be able to evaluate the pathological burden of tau in the brain. Accurate biomarker measurements are expected to contribute to the precise classification of AD patients.
Session	Theme A: β-Amyloid Diseases / A04.h. Imaging, Biomarkers, Diagnostics: CSF- and blood-based biomarkers (SHIFT 01-454)

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