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【Overview presentation】

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Development of plasma p-tau231 assay on a fully automated immunoassay system

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Overview presentation	**Objectives** Biomarker profiling, such as ATN classification, is actively being studied to characterize the pathological processes in different stages of Alzheimer's disease (AD). Recently, many studies have focused on plasma phosphorylated tau (p-tau), which is known to have multiple molecular species with different phosphorylation sites. It has been pointed out that each of these species may exhibit concentration changes at different disease stages. Therefore, measuring simultaneously multiple p-tau species with other ATN biomarkers may allow more detailed biomarker profiling. High sensitive, simple and high performing methods in plasma will accelerate such studies and improve clinical trial set-up. Previously, we have developed the fully automated assays for measuring plasma Aβ40, Aβ42, tau, neurofilament light chain, and p-tau181. In this study, as a candidate of multi p-tau spieces, a newly developed p-tau231 assay was analytically and clinically explored on our immunoassay platform (HISCL™ series). **Methods** We developed the plasma p-tau231 assay using HISCL series, which can achieve highly precise, sensitive, and rapid measurements. Analytical characteristics, such as dilutional linearity and repeatability were evaluated. We measured plasma p-tau231 in commercially available plasma samples from cognitive normal (CN) and from patients with clinically diagnosed AD.

	Results Developed assay had the required performance characteristics to measure p-tau231 levels in CN plasma. The dilution linearity and repeatability met established criteria. There was a significant difference in the concentration of plasma p-tau231 between the AD and CN groups. **Conclusion** A novel plasma p-tau231 assay has sufficient performance to measure p-tau231 levels in plasma. Disease-dependent concentration changes in plasma samples were also observed, suggesting that p-tau231 may have potential values in more precise staging in AD pathology to be coupled with other ATN biomarkers and other p-tau species.
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