

Sysmex Presents Academic Report in Effort to Create a Simple Blood Test to Diagnose Alzheimer's Disease

The Content Presented at the International Conference on Alzheimer's & Parkinson's Diseases:
(AD/PD™ 2022)

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu; hereafter, "Sysmex") and Eisai Co., Ltd. (Headquarters: Tokyo; CEO: Haruo Naito; hereafter, "Eisai") are aiming to leverage their individual technologies and expertise in the creation of next-generation diagnostic agents that may aid in early diagnosis of dementia, treatment selection, and regular confirmation of treatment efficacy. Sysmex and Eisai have a non-exclusive comprehensive agreement for the creation of novel diagnostic agents for the dementia area.

Sysmex and Eisai announced today that an oral presentation on the use of the HISCL™ Automated Immunoassay System in the clinical evaluation of the plasma A β ₁₋₄₂/A β ₁₋₄₀ ratio was delivered at the International Conference on Alzheimer's & Parkinson's Diseases (AD/PD™ 2022) held in Barcelona, Spain from March 15 to 20 2022.

Presentation title	Fully Automated Plasma Beta-Amyloid Immunoassays Predict Amyloid Pathology Defined by Amyloid PET
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Type of presentation	Virtual, On-Demand Oral

<p>Overview of presentation</p>	<p>Accumulation of β-amyloid peptide ($A\beta$) (amyloid pathology) in the brain is a hallmark of Alzheimer's disease (AD). Several clinical trials on disease-modifying therapies (DMTs) targeting $A\beta$ have been conducted. The US Food and Drug Administration has recently granted accelerated approval for an anti-amyloid antibody for early AD. Given this background, there is an increasing need for simple, cost-effective diagnostic methods of detecting amyloid pathology in the brain.</p> <p>Our group previously reported that amyloid PET status was correlated with $A\beta_{1-42}/A\beta_{1-40}$ ratio in plasma (hereafter, "plasma $A\beta$ ratio") and that amyloid pathology in the brain could potentially be predicted using blood biomarkers.*¹ Our research has focused on the plasma $A\beta$ ratio using clinical specimens. In this presentation, we conducted a clinical evaluation of the plasma $A\beta$ ratio measured using the HISCL Automated Immunoassay System (Sysmex) in comparison with amyloid PET status determined by the Centiloid method*² in 180 patients (Discovery Study) and 191 patients (Validation Study) clinically diagnosed with mild AD or mild cognitive impairment.</p> <p>(Results)</p> <ul style="list-style-type: none"> ✓ In the Discovery Study, the plasma $A\beta$ ratio was significantly lower in the Amyloid PET positive group as compared to the negative group and it predicted amyloid PET status with high accuracy: sensitivity 97.5%, specificity 80.8%, AUC = 0.93 (0.90 – 0.97). ✓ In the Discovery Study, the plasma $A\beta$ ratio and Centiloid unit (CL) were significantly correlated with a Spearman rank correlation coefficient*³ of -0.75 ($P < 0.001$), and this indicates that our assay could be indicative of the amount of $A\beta$ accumulation in the brain. Also, we observed inconsistency in several patients, who had a positive plasma $A\beta$ ratio and a negative CL. This inconsistency has also been found in other studies and it was reported that it represented an increased risk of conversion to PET positive as compared to $A\beta$ ratio negative subjects.*⁴ Our results suggest that the plasma $A\beta$ ratio measured using the HISCL Automated Immunoassay System could potentially indicate presence of amyloid pathology in the brain at an earlier stage when it was not detectable by PET. <p>Since measurement of plasma $A\beta_{1-42}$ and $A\beta_{1-40}$ in the HISCL is fully automated immunoassay that is less invasive and more accessible, it may contribute to the diagnosis of AD in routine clinical practice. We believe that the plasma $A\beta$ can contribute to early diagnosis, of AD, treatment selection and monitoring of treatment effect.</p>
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[Notes]

*1 The 18th R&D Meeting (2021, Sysmex)

*2 Klunk WE et al, *Alzheimer's Dementia* (2014)

*3 Shows significant correlation between data from 2 quantitative data distributions. In the present analysis, we calculated Spearman's rank correlation coefficients, which indicate correlations between rank data.

*4 Schindler SE et al, *Neurology*, 93, e1647-e1659 (2019)