March 22, 2022
Sysmex Corporation

# 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 ADx Neurosciences (HQ: Ghent, Belgium; CEO: Koen Dewaele) are conducting joint research on the construction of a blood biomarker measurement system for dementia.

Sysmex Corporation announced today that an oral presentation on the basic evaluation of novel assay reagents for measurement of plasma $A\beta_{1-40}$, $A\beta_{1-42}$, p-Tau 181, t-Tau (total Tau) and NfL using an HISCL™ fully automated immunoassay system had been delivered at the International Conference on Alzheimer's & Parkinson's Diseases (AD/PD™ 2022) held from March 15 to 20, 2022 in Barcelona, Spain.

| | |
|---|---|
| Presentation title | Plasma Biomarkers for Classification of AD Pathology by a Fully Automated Immunoassay System (HISCL™ series) |
| Authors | Kengo Ishiki[1], Shunsuke Watanabe[1], Kazuto Yamashita[1], Teresa Lukaszewska[2], Masahiro Miura[1], Yasuhiro Irino[1], Shigeki Iwanaga[1], Toshiyuki Sato[1], Eugeen Vanmechelen[3], Tomokazu Yoshida[1]<br>[1]Central Research Laboratories, Sysmex Corporation, Kobe, Japan; [2]Sysmex R&D Center Americas Inc., Mundelein, Illinois, USA; [3]ADx Neurosciences, Ghent, Belgium |
| Type of presentation | Virtual, On-Demand Oral |
| Overview of presentation | The ATN (A: Amyloid pathology, T: Tau pathology, N: neurodegeneration/neurological injury) classification is widely used in research as a means of classifying Alzheimer's disease (AD) based on pathology. At present, cerebrospinal fluid (CSF) test and neuroimaging test are necessary, but it is thought to be desirable to establish a simple ATN classification system such as blood test in order to accelerate clinical application. Our group has previously reported the development of novel assays for the measurement of plasma $A\beta_{1-40}$, $A\beta_{1-42}$, plasma p-Tau 181[*1] and plasma t-Tau using an HISCL fully automated immunoassay system (Sysmex) and the fact that significant differences were observed between AD patients and a normal cognitive function (CN)subjects. |

| | |
|---|---|
| | In the present study, we developed a measuring reagent for neurofilament light chain protein (NfL) as a new candidate for the “N” category, with use of an HISCL immunoassay system. We also verified clinical performance for $A\beta_{1\text{-}40}$, $A\beta_{1\text{-}42}$, p-Tau 181, Tau and NfL reagent using commercially available plasma and cerebrospinal fluid (CSF) samples from mild cognitive impairment (MCI) and Alzheimer’s disease (AD) patients, and CN subjects.<br>(Results)<br>・ Analytical performance (repeatability, dilution linearity, spike and recovery) achieved for p-Tau 181, Tau and NfL using plasma samples showed enough analytical performance to measure plasma biomarkers.<br>・ The results for correlations (Spearman’s rank correlation coefficients*2) between plasma and CSF were rs=0.49 for p-Tau 181 ($p< 0.001$), rs=0.40 for Tau ($p<0.005$) and rs=0.37 for NfL ($p<0.001$) suggesting that plasma biomarkers levels reflect the situation in the brain.<br><br>The above results suggested that plasma p-Tau 181 is a suitable candidate for the “T” category and that both plasma Tau and NfL may reflect neurodegeneration (category “N”) |

**[**Notes**]**

*1 It stands for phosphorylated tau protein. 181 indicates that the phosphorylation site of threonine 181, the 181st amino acid of the tau protein, is phosphorylated.

*2 Shows the extent of 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.