

June 27, 2022
Sysmex Corporation

Completion of Declaration of Conformity to the European IVD Directive for an Assay Kit that Measures Plasma Amyloid Beta (A β) Using the Automated Immunoassay System HISCLTM-5000/HISCLTM-800

- Testing Method that Assists in the Identification of A β Accumulation in the Brain -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announces that it has completed a declaration of conformity to the European IVD Directive for an assay kit to measure A β in the blood using its automated immunoassay system HISCL-5000/HISCL-800 ("the assay kit").

The number of patients with dementia is rising each year in line with the global increase in life expectancy. Currently more than 55 million people live with dementia worldwide, and there are nearly 10 million new cases every year.*

Alzheimer's disease, which accounts for about 60–70% of dementia, is thought to be caused by a protein called A β accumulating in the brain and damaging nerve cells. Once the nerve cells have been damaged, they cannot be regenerated, so it is important that the disease is diagnosed at the earliest stage, and that treatment is initiated as soon as possible.

In order to diagnose Alzheimer's disease, technology to identify the accumulation of A β in the brain is required, but conventional testing methods are not always easy to perform because of the cost and the physical burden associated with them.

Sysmex has been engaged in the development of an easy-to-use technology to identify the accumulation of A β in the brain to help solve these issues. In February 2016, Sysmex and Eisai Co., Ltd. entered into a comprehensive, non-exclusive collaboration agreement for the creation of new diagnostic reagents in the field of dementia. By utilizing each other's technologies and knowledge, Sysmex has been engaged in the development of next-generation diagnostic reagents that will enable the early diagnosis of dementia, the selection of treatment options, and the monitoring of treatment effects.

On May 17, 2022, Sysmex completed a declaration of conformity to the European IVD Directive for the assay kit that assists in the identification of A β accumulation in the brain by measuring plasma A β using the Automated Immunoassay System HISCL-5000/HISCL-800.

It is expected that the assay kit with quality and performance as an IVD will help promoting research activities in Europe not only for developing new diagnosis procedures but for drug development as well, by utilizing the advantages of plasma biomarkers to allow easy and frequent measurement.

By contributing to the acceleration of clinical implementation of these research results, Sysmex is promoting activities to provide the early provision of value for the medical treatment of Alzheimer's disease.

Reference

January 5, 2022 press release entitled: "Sysmex Files for Manufacturing and Marketing Approval for an Assay Kit that Assists in Identification of Amyloid Beta (A β) Accumulation in the Brain"

<https://www.sysmex.co.jp/en/news/2022/pdf/220105.pdf>

Terminology

- * Source: Website of World Health Organization
<https://www.who.int/news-room/fact-sheets/detail/dementia>

Sysmex's Materiality

Sysmex has identified "Resolution of medical issues through products and services" as one of the issues that we prioritize (materiality), and is working to solve medical issues through its business activities. Leveraging our proprietary technology and the global network that we have cultivated thus far, we continue to strive to contribute to the development of healthcare and the healthy lives of people.



The purpose of this press release is to communicate our business activities to our stakeholders. It may or may not include information about Sysmex's products or their research and development, but this is not intended for promotion, advertising or medical advice. The information contained in this press release is current as of the date of the announcement but may be subject to change without prior notice.