

December 22, 2022  
Sysmex Corporation

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## Sysmex Receives Manufacturing and Marketing Approval for an Assay Kit to Identify Amyloid Beta (A $\beta$ ) Accumulation in the Brain, a Cause of Alzheimer's Disease, Using a Small Amount of Blood

– Measurement of Plasma A $\beta$  Using Automated Immunoassay System HISCL™-5000/HISCL™-800 –

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On December 19, 2022, Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) received manufacturing and marketing approval in Japan for the HISCL  $\beta$ -Amyloid 1-42 Assay Kit and the HISCL  $\beta$ -Amyloid 1-40 Assay Kit (collectively, “the Product”) as *in vitro* diagnostics to measure amyloid beta (A $\beta$ ) in the blood. The Product assists in identifying A $\beta$  accumulation in the brain, which is a characteristic of Alzheimer's disease, by measuring A $\beta$  levels in the blood using the company's automated immunoassay system HISCL-5000/HISCL-800 (the “HISCL-Series”). We will prepare for market introduction in Japan to give patients access to this minimally invasive and simple test as soon as possible.

Currently, more than 55 million people worldwide suffer from dementia, and with increasing life expectancy, this number is expected to rise to 130 million by 2050.\* Alzheimer's disease, which is the most common form of dementia and accounts for approximately 60%-70% of all cases, is caused by A $\beta$  peptides accumulating in the brain, resulting in damage to nerve cells. Once damaged, it is difficult for nerve cells to regenerate, so early diagnosis and treatment are essential.

The diagnosis of Alzheimer's disease requires technology to identify the accumulation of A $\beta$  in the brain. However, conventional testing methods have issues in terms of their invasiveness and cost, so there is a demand for less invasive and simpler testing and diagnostic techniques.

In recent years, there has been an increase in the development of new therapeutic drugs worldwide that address the underlying pathology of Alzheimer's disease, so testing and diagnosis are becoming even more important for the appropriate use and dissemination of these drugs.

Sysmex has been developing a technology to more quickly and readily identify the accumulation of A $\beta$  in the brain in order to solve issues in the diagnosis of Alzheimer's disease. 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, and have been developing the Product by utilizing each company's technologies and knowledge. On December 28, 2021, Sysmex submitted an application for manufacturing and marketing approval for the Product to Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

The newly approved Product assists in identifying the level of accumulation of A $\beta$  in the brain by measuring the ratio of A $\beta$  peptides (the 1-42 peptide and 1-40 peptide) in the blood using Sysmex's HISCL-Series, which employs chemiluminescence enzyme immunoassay (CLEIA) as its measurement principle. Unlike conventional testing methods, the Product allows testing with blood, thus reducing the physical, emotional, and financial burden on patients with suspected A $\beta$

accumulation in the brain. Furthermore, the product is expected to contribute to early diagnosis and early determination of optimal treatment plans for patients. In addition, automated assays using the HISCL-Series— which requires only 10 to 30  $\mu$ L of blood (plasma) with a measurement time of just 17 minutes—will also help improve the efficiency and standardization of testing.

In order to expand opportunities for patients to receive this testing, we plan to prepare for the early introduction of the Product to the market, while working toward its coverage by Japanese national health insurance.

Sysmex will continue to develop testing and diagnostic techniques that reduce the burden on patients with Alzheimer's disease and promote the widespread use of the technologies we develop in Japan and overseas, thereby creating an environment in which healthcare professionals can begin treatment of the disease as soon as possible. At the same time, we will strive to improve the QOL of patients and their families.

### Product Overview

Generic name:	$\beta$ -amyloid kit	$\beta$ -amyloid kit
Product name:	HISCL™ $\beta$ -Amyloid 1-42 Assay Kit	HISCL™ $\beta$ -Amyloid 1-40 Assay Kit
Registration number in Japan:	30400EZX00104000	30400EZX00105000
Intended use:	Quantitative measurement of $\beta$ -amyloid 1-42 in plasma (to assist in identifying the level of accumulation of A $\beta$ in the brain)	Quantitative measurement of $\beta$ -amyloid 1-40 in plasma (to assist in identifying the level of accumulation of A $\beta$ in the brain)
Manufactured and distributed by:	Sysmex Corporation	
Target market:	Japan	

### Reference

February 15, 2016 news release: “Sysmex and Eisai enter comprehensive agreement to create next-generation diagnostic reagents in the field of dementia”

<https://www.sysmex.co.jp/en/news/2016/160215.html>

January 5, 2022 news release: “Sysmex Files for Manufacturing and Marketing Approval for an Assay Kit that Assists in Identification of Amyloid Beta (A $\beta$ ) Accumulation in the Brain

-Measurement of Plasma A $\beta$  Using Automated Immunoassay System

HISCL™-5000/HISCL™-800-”

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

### Terminology

\*Source: Global status report on the public health response to dementia executive summary (Sep. 2, 2021, World Health Organization)

<https://apps.who.int/iris/bitstream/handle/10665/344707/9789240034624-eng.pdf>

### **Sysmex's Materiality**

Sysmex has identified “Resolution of medical issues through products and services” as one of the issues that we prioritize (materiality) as we work to develop and supply products with high clinical value. 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.



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