

February 7, 2024
Sysmex Corporation
Hitachi High-Tech Corporation

Sysmex and Hitachi High-Tech Agree to Collaborate on Development of New Genetic Testing Systems

Sysmex Corporation (HQ: Kobe, Japan; President: Kaoru Asano; hereafter “Sysmex”) and Hitachi High-Tech Corporation (HQ: Minato-ku, Tokyo, Japan; Representative Director and President: Takashi Iizumi; hereafter, “Hitachi High-Tech”) announce that both companies have agreed to collaborate in the development of genetic testing systems based on capillary electrophoresis sequencers (CE sequencers)¹. This decision comes from discussions based on the findings of joint research carried out since the conclusion of a feasibility study (FS) agreement in August 2023 aimed at developing new genetic testing systems. To achieve widespread clinical realization, Sysmex and Hitachi High-Tech will develop more efficient genetic testing systems at a lower cost, aiming at expanding optimal genetic testing for individual diseases.

In recent years, there has been active development of assay reagents using next generation sequencer (NGS)² in the genetic testing field. However, such challenges as shortening measurement times and reducing running costs have emerged, necessitating the development of new genetic testing systems that can be widely adopted in the clinical setting.

In order to resolve these issues arisen in clinical setting, the companies concluded the FS agreement in August 2023 to jointly study possibilities for the development of new genetic testing systems enabling optimal genetic analysis for individual diseases by combining Hitachi High-Tech’s CE sequencer technology and Sysmex’s knowhow in NGS reagent development and analysis technology accumulated through the clinical realization of genomic medicine to date.

Having achieved the milestones in the FS agreement, Sysmex and Hitachi High-Tech have agreed, as the next step, to collaborate on the development of genetic testing systems with a view to their widespread adoption in the clinical setting. Hitachi High-Tech will proceed with obtaining approval for CE sequencers as medical devices and Sysmex will go ahead with development and regulatory approval for testing reagents for use with such devices, and develop analysis software. Both companies will first work on clinical application in the oncology area and then aim to expand gradually to other disease areas.

Maximizing the use of the individual technologies and knowhow, the two companies aim to achieve the spread of new genetic testing systems that provide shorter measurement times and reduced running costs.

Reference

Efforts of Both Companies Towards the Clinical Realization of Genomic Medicine

Sysmex has been endeavoring to create high-value testing and diagnostic technologies to support optimal medical care tailored to each patient. With a view to achieving personalized medicine, the entire Sysmex group has been working together toward the clinical realization of genomic medicine. Regulatory approval and insurance coverage has been gained for a cancer genomic profiling testing system and a gene panel testing system for inherited retinal dystrophy (IRD), both firsts in Japan.

Hitachi High-Tech's healthcare business provides new value in the healthcare field by integrating cutting-edge "analysis and automation technologies" with digital technology. Hitachi High-Tech group have contributed to improve quality and efficiency of testing with a product lineup that includes in-vitro diagnostic equipment that analyzes blood and other specimens to support the diagnosis of diseases, and DNA sequencers that contribute to genomic medicine. By entering the molecular diagnostics business, Hitachi High-Tech aims to contribute to the improvement of people's QoL (Quality of Life) through "personalized medicine" and "sophisticated diagnosis of intractable diseases."

Terminology

- 1 Capillary electrophoresis sequencer:
Analysis instrument that analyzes DNA base sequences and base lengths in a short time, at relatively low cost. It is widely used in the medical and healthcare areas for analyzing individual DNA differences as well as in DNA identification in criminal investigations.
- 2 Next generation sequencer (NGS):
Analysis instrument that simultaneously and parallelly reads and analyzes massive volumes of genetic information containing DNA bases and sequences.

About Sysmex Corporation

Sysmex Corporation, headquartered in Kobe, Japan, is a global leader in *in vitro* diagnostics. Since its foundation in 1968, Sysmex has focused on diagnostics as the core of its business, and today, it supports the health of people in over 190 countries and regions worldwide. Sysmex continues to innovate in diagnostics, and to collaboratively create unique values in the areas of personalized medicine and novel treatments, under its long-term vision of "Together for a better healthcare journey." Through its unique technology, solutions, and co-creation with various partners, Sysmex delivers new value and addresses the universal desire of people to live longer and healthier lives. For more information about Sysmex, please visit www.sysmex.co.jp/en/.

About Hitachi High-Tech

Hitachi High-Tech, headquartered in Tokyo, Japan, is engaged in activities in a broad range of fields, including manufacture and sales of clinical analyzers, biotechnology products, and analytical instruments, semiconductor manufacturing equipment and analysis equipment. and providing high value-added solutions in fields of social & industrial infrastructures and mobility, etc. The company's consolidated revenues for FY 2022 were approx. JPY 674.2 billion. For further information, visit <http://www.hitachi-hightech.com/global/en/>

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.

Information contained in this news release is current as of the date of the press announcement, but may be subject to change without prior notice.
