
Sysmex Forms Strategic Alliance with QIAGEN for Providing Global Cancer Companion Diagnostics that Uses Ultra-sensitive Liquid Biopsy NGS Technology

Sysmex Corporation (HQ: Kobe, Japan, Chairman and CEO: Hisashi Ietsugu) has announced today that it has formed a global strategic alliance with QIAGEN N.V. (HQ: Hilden, Germany, CEO: Thierry Bernard) for the development of cancer companion diagnostics.¹

Sysmex is working to strengthen its global relationship with pharmaceutical companies in order to develop companion diagnostics and timely launch them by capitalizing on Plasma-Safe-SeqS technology,² a liquid biopsy³ developed by Sysmex using a next-generation sequencer (NGS),⁴ while leveraging QIAGEN's experience in developing companion diagnostics.

The effective cancer treatment requires companion diagnostics that identifies drug treatment suitable to patients. For the past few years, growing attention has been focused on companion diagnostics based on blood testing (liquid biopsy testing), which reduces the physical burden on the patients.

Sysmex currently offers the "OncoBEAM^{TM5} RAS CRC Kit" as companion diagnostics for colorectal cancer. It uses highly-sensitive digital PCR technology, and is regulatory approved and covered by national insurance in Japan. In addition to this, the ultra-sensitive liquid biopsy testing utilizing NGS is also being developed and offered via CRO service for pharmaceutical companies and research use only kits.

Following this, Sysmex has entered into a global strategic alliance with QIAGEN, a company with extensive experience in companion diagnostics in the oncology field. This alliance is intended to promote early clinical implementation of ultra-sensitive liquid biopsy companion diagnostics using Plasma-Safe-SeqS technology by expediting field work with pharmaceutical companies that develop molecularly targeted drugs for cancer.

Sysmex will continue to contribute to the improvement of patients' quality of life (QOL), the standardization of medical care, and the advancement of personalized medicine by developing and disseminating tests with significant clinical value.

References

August 2, 2019 news release: "Sysmex Obtains First Manufacturing and Marketing Approval in Japan for Blood-Based RAS Gene Mutation Testing for Colorectal Cancer"

<https://www.sysmex.co.jp/en/news/2019/190802.html>

March 5, 2020 news release: "Sysmex Presents Academic Report Related to the Clinical Utility of RAS Gene Mutation Testing for Colorectal Cancer Using Liquid Biopsy"

https://www.sysmex.co.jp/en/news/2020/pdf/200305_02_e.pdf

August 3, 2020 news release: “Insurance Coverage Received for Liquid Biopsy RAS Gene Mutation Testing for Colorectal Cancer Using High-Sensitivity Digital PCR”

<https://www.sysmex.co.jp/en/news/2020/pdf/200803.pdf>

Terminology

- 1 Companion diagnostics:
Test to predict the efficacy or risk of side effects of specific drugs before prescription.

- 2 Plasma-Safe-SeqS technology:
By tagging each molecule of a gene fragment to be analyzed, this technology allows differentiation between true genetic mutations and errors (errors generated in the process of preparing and reading NGS samples). One of the vital issues with traditional NGS is the existence of a certain possibility of error in principle, which always brings doubts to the mutation detection results on whether it is a true mutation or a false positive generated from reading errors. Plasma-Safe-SeqS technology is expected to be the solution to this problem.

- 3 Liquid biopsy:
A type of biopsy based mainly on the blood. It is designed to impose less burden on the patient, while having the performance equivalent to that of a conventional biopsy collected from solid tissue, such as a tumor dissection.

- 4 Next-generation sequencer (NGS):
An analyzer capable of simultaneously sequencing large quantities of DNA molecules in parallel.

- 5 OncoBEAM:
The name of Sysmex’s product to detect minute gene mutations circulating in the blood with a high degree of sensitivity using BEAMing technology. BEAMing technology is a gene analysis method combining digital PCR and flow cytometry technologies for highly sensitive analysis of genetic mutations.

About Sysmex

Sysmex Corporation is a world leader in clinical laboratory systemization and solutions, including laboratory diagnostics, laboratory automation and clinical information systems. Serving customers for more than 50 years, Sysmex focuses on technological leadership in diagnostic science and information tools that make a difference in the health of people worldwide. The company is also exploring emerging opportunities in the life science field. Its R&D efforts focus on the development of high-value-added testing and diagnostic technologies that are innovative, original and optimize individual health. Sysmex also seeks to leverage its state-of-the-art technologies for cell, gene and protein analysis. The company, headquartered in Kobe, Japan, has subsidiaries in North America, Latin America, Europe, the Middle East, Africa, China and Asia Pacific and employs more than 9,000 employees worldwide. Sysmex Corporation is listed on the first section of the Tokyo Stock Exchange. For more information about Sysmex Corporation and its affiliate companies, please visit <http://www.sysmex.co.jp/en/>.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare) and Life Sciences (academia, pharma R&D and industrial applications, primarily forensics). As of December 31, 2020, QIAGEN employed approximately 5,600 people in over 35 locations worldwide. Further information can be found at <http://www.qiagen.com>.

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