

News Release

Konica Minolta Obtains Manufacturing and Marketing Approval for its GenMineTOP Cancer Genome Profiling System from the Ministry of Health, Labour and Welfare

This is a translation of the original Japanese language news release on July 15, 2022. In the event of discrepancies, the original Japanese language shall prevail.

Tokyo (July 15, 2022) – Konica Minolta, Inc. (Konica Minolta) is pleased to announce that on July 13, its group company, Konica Minolta REALM, Inc., obtained manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for its GenMineTOP Cancer Genome Profiling System, which can analyze both DNA and RNA genetic information in Japan.

This system is the result of joint research and development of next-generation oncogenic gene panels by the University of Tokyo, the National Cancer Center Research Institute, and Konica Minolta*1 that has taken place since June 2019. The system can analyze a patient's DNA and RNA gene mutation information (data) obtained from solid tumor tissue specimens and compare against the DNA from the patient's non-tumor cells*2.

Paired analysis*3 of tumor tissue and non-cancerous cell-derived base sequences using this system's comprehensive cancer genome profiling*4 can detect mutations (base substitutions, insertions/deletions and copy number alterations) of 737 cancer-associated genes (DNA) involved in cancer diagnosis and treatment, and RNA mutations (fusion, exon skipping) and information on the RNA expression level collectively. Output results of comprehensive genome profiling using this system can be used to support decisions on diagnostic and treatment policies in patients with solid cancers.

Through this system, Konica Minolta is helping improve patients' QOL (Quality of Life) by providing a detailed cancer diagnosis that physicians can use to create treatment plans tailored to the specific health characteristics of the individual.

In response to the presently obtained approval, Junji Tashiro, the Representative Director and President of Konica Minolta REALM, Inc., commented: "We are pleased that our GenMineTOP Cancer Genome Profiling System has been approved. We will enhance patient care by providing health care professionals critical information that they can use to create specific treatment plans for their patients. We will also prepare to provide insurance reimbursement of the system in the future."

System Overview

Generic name: Gene mutation analysis program (for use in cancer genome profiling)

Trade name: GenMineTOP Cancer Genome Profiling System

(Approval No.: 30400BZX00155000)

Features

- Can analyze 737 cancer-associated genes (DNA).
- Can reveal fusion genes, exon skipping, and RNA expression level.
- Can analyze information on gene mutations from tumor tissue specimens and noncancer cells.
- *1 News release by Konica Minolta dated June 6, 2019 "Konica Minolta to Join Global Oncogenic Gene Panel Research: Move Strengthens Konica Minolta's Advance into Personalized Medicine in Japan with Next-Generation Screening Capabilities."
- *2 Non-tumor cell: A normal cell that is not cancerous. Blood is used for this profiling.
- *3 Pair analysis: Simultaneous analysis not only of cancer tissue gene sequences, but also of non-tumor cell gene sequences among cancer genome profiling.
- *4 Cancer genome profiling: Simultaneous analysis of multiple gene mutations, amplifications, and fusions in a tumor that are important for cancer management.

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