

April 3, 2018

Advanced Medical Care Approval Received for Multiplex Gene Panel Testing to Advancing Personalized Medicine

On April 1, 2018, Multiplex Gene Panel Testing to Advancing Personalized Medicine using the system developed jointly by the National Cancer Center (Location: Tokyo, Japan; President: Hitoshi Nakagama) and Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) received approval as Advanced Medical Care¹. We will begin providing this testing from April 9, 2018.

In addition to a confirmed diagnosis, cancer treatment requires numerous tests using genes and proteins for efficacy prediction, recurrence monitoring, and other aspects of treatment. Among these tests, attention is being focused on clinical cancer sequence testing which analyzes changes in cancer-specific genes for the patient, and elicits useful information to help in cancer diagnosis and treatment by measuring many genes in cancer tissues at once.

The National Cancer Center and Sysmex have been working to further promote the development of new methods of cancer diagnosis. In October 2015 the Sysmex Cancer Innovation Laboratory, which meets international quality standards, opened within the National Cancer Center Hospital. We are also pursuing the joint development of a cancer-related gene panel² testing system. This system employs a gene diagnostic panel developed by the National Cancer Center (NCC Oncopanel) and a next-generation sequencer³ for measurement, to conduct comprehensive genetic analysis of patient tissue to assist in determining treatment methods, including drug administration. In addition, to achieve early application in clinical settings, we have conducted a clinical study at the National Cancer Center Hospital as part of the TOP-GEAR Project, and the system has received designation under the *Sakigake* Designation System⁴ for *in vitro* diagnostic pharmaceuticals and medical devices⁵. At the same time, we have submitted an Advanced Medical Care application for the Multiplex Gene Panel Testing to Advancing Personalized Medicine using the system.

On April 1, 2018, we received approval as Advanced Medical Care for the testing. As a result, we plan to begin providing the testing at the National Cancer Center Hospital on

April 9, 2018. We also plan to begin conducting such testing at institutions cooperating in the provision of advanced medical care, to expand opportunities for patients to receive this testing.

All of the samples obtained in this testing will be measured by RIKEN GENESIS Co., Ltd. (HQ: Tokyo, Japan; President & CEO: Naoto Kondo), a Sysmex affiliate that provides lab-assay services for genetic testing, at the Innovation Genome Center (Kawasaki Office).

The National Cancer Center, Sysmex and RIKEN GENESIS are undertaking initiatives targeting Advanced Medical Care, and working to obtain *in vitro* diagnostic pharmaceuticals and medical devices approval for the system under the *Sakigake* Designation System. As a result, we are aiming for the early realization at clinics of the testing and contributing to the development of personalized medicine.

Terminology

1 Advanced Medical Care:

Refers to healthcare technologies that have been approved by Japan's Minister of Health, Labour and Welfare but are not yet covered by healthcare insurance. Based on a "fundamental accord" in December 2004 between the Minister of Health, Labour and Welfare; the Cabinet Officer Minister of State in Charge of Special Missions (regulatory reform, industrial revitalization); the minister in charge of administrative reform; and the minister in charge of special zones for structural reform and regional revitalization, this system was approved in combination with healthcare insurance coverage from the perspective of ensuring the safety of Japanese citizens, preventing patient burdens from increasing, expanding citizens' choices and increasing convenience.

2 Cancer-related gene panel:

A diagnostic reagent kit that is designated to analyze the mutation, proliferation and fusion of multiple genes having diagnostic significance for cancer. NCC Oncopanel, a gene diagnosis panel developed mainly by the National Cancer Center, was created to appropriately diagnose gene mutations characteristic of Japanese patients.

3 Next-generation sequencer:

An analyzer capable of simultaneously reading large quantities of DNA bases and

sequences that contain genetic information.

4 *Sakigake* Designation System:

This system was designed to fast-track the provision of leading-edge global therapeutic drugs to Japanese patients. Novel drugs that satisfy the four conditions outlined below may be designated under the *Sakigake* Designation System at a comparatively early stage of development, and are given priority in clinical trial consultation and review. The system also aims to encourage applicants to create production systems in accordance with the approval review schedule and putting these into practical use more quickly by facilitating post-approval provision in medical settings. Four designation conditions apply: (1) an innovative mechanism of action, (2) targeting serious or life-threatening diseases, (3) demonstrated effectiveness, and (4) the treatment is being developed and receiving targeting approval in Japan prior to other countries.

5 The cancer-related gene panel testing system was approved under designation number: Sakigake screening (28) No. 1; with a designation date of February 28, 2017.

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