

March 27, 2020
Sysmex Corporation

Sysmex Obtains First Marketing Approval in Japan for the Novel Coronavirus Nucleic Acid Detection Kits (RT-PCR Method)

- Aiming for early introduction of test kits for *in vitro* diagnostic medical devices in medical institutions -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) has obtained first marketing approval in Japan for an *in vitro* diagnostic medical device, “2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit”. Delivery of this product to medical institutions is scheduled for March 2020.

When used in combination with a real-time PCR instrument, this product detects the RNA of the novel coronavirus (severe acute respiratory syndrome coronavirus 2, “SARS-CoV-2”) extracted from sample of upper respiratory tract (nasopharyngeal swabs) or sample of lower respiratory tract (sputum or bronchoalveolar lavage fluids). The test results of this product will be used to help diagnose SARS-CoV-2 infection.

After the first case was confirmed in January 2020, one case after another of SARS-CoV-2 infection (coronavirus disease 2019, hereinafter, “COVID-19”) has been reported in Japan. In order to promote measures against COVID-19 both comprehensively and effectively, the Japanese government has established the Novel Coronavirus Response Headquarters within the Cabinet to direct its efforts to prevent the spread and severity of infections. To this end, it is imperative to put a clinical testing structure in place for the diagnosis of patients.

Sysmex is promoting the “resolution of medical issues through products and services” as one of its priority issues (materiality), thereby tapping into its proprietary technologies and global networks to contribute to the development of healthcare and the healthy lives of people. As part of its effort to halt the further spread of COVID-19 and prevent the condition of patients from worsening, Sysmex has signed a basic distributor agreement with BGI Genomics, which owns novel coronavirus nucleic acid detection kits which have received orders from more than 50 countries worldwide after marketing approval in China and CE marking certification. Since then, Sysmex has been working to obtain marketing approval for the provision of the kits to clinical setting in Japan.

On March 27, 2020, Sysmex obtained marketing approval of the 2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit. When used in combination with a real-time PCR instrument, this product detects the RNA of SARS-CoV-2 extracted from sample of upper respiratory tract (nasopharyngeal swabs) or sample of lower respiratory tract (sputum or bronchoalveolar lavage fluids). The test results of this product will be used to help diagnose SARS-CoV-2 infection. Through the provision of this product, Sysmex will help medical institutions authorized to perform tests of designated infectious diseases to implement a COVID-19 clinical testing structure. Delivery of this product to medical institutions is scheduled for March 2020.

While sincerely hoping for the early containment of the spread of COVID-19, we at Sysmex will dedicate ourselves to the provision of reliable healthcare and the realization of good health for all by providing a stable supply of *in vitro* diagnostic medical devices that are in high social demand, through good teamwork with partners both within and outside the Group.

Product Overview

Generic name: SARS-CoV-2 nucleic acid detection kit (84014000)
Name: 2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit
(*in vitro* diagnostic medical device registration number:
30200EZX00017000)
Target market: Japan
Manufactured/marketed by: Sysmex Corporation
PCR instruments: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument
(from Thermo Fisher Scientific, marketing notification number:
13B1X10227000001) or its equivalent genetic analyzer

Overview of BGI Genomics

Company name: BGI Genomics
Established: July 9, 2010
Line of business: BGI Genomics is the world's leading provider of genomic sequencing services and proteomic services, now serving customers in more than 100 countries. We provide academic institutions, pharmaceutical companies, health care providers and other organizations with integrated genomic sequencing and proteomic services and solutions across a broad range of applications spanning basic research covering human, plant, animal, and microbial species; clinical research in human health; genetic testing and screening, etc.
Location: Building No.7, BGI Park, No.21 Hongan 3rd Street, Yantian District, Shenzhen 518083, China
Representative: Yin Ye (尹烨)