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News Release

April 15, 2021
Sysmex Corporation

Sysmex Obtains Manufacturing and Marketing Approval for Novel Coronavirus Detection Reagent (RT-PCR Method)

- Building a Self-Sufficient Production System in Japan for a Stable Supply of PCR Testing Kits -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced today that on April 14, 2021, it obtained *in vitro* diagnostic approval in Japan for the manufacturing and marketing of the DetectAmp SARS-CoV-2 RT-PCR Kit, a SARS coronavirus nucleic acid kit that detects the RNA of the novel coronavirus (SARS-CoV-2). The company received insurance coverage for the kit on the same date.
This product will make it possible to reduce the PCR reaction time and detect the RNA of SARS-CoV-2 with high sensitivity.

PCR testing, a primary procedure for diagnosing coronavirus disease 2019 (COVID-19), is being performed on approximately 20,000 persons daily, and a total of 9.82 million tests were conducted in Japan by the April 10, 2021.[1]
As the global demand for PCR testing increased rapidly due to the pandemic, Japan experienced supply shortages of PCR testing reagents and their raw materials because it relied on overseas sources for these supplies. As a result, the delay in making PCR testing widely available has grown to become a social problem.[2] In Japan, as the number of COVID-19 infections increases, it will be essential to enhance a testing system and ensure a stable supply of PCR tests and other reagents.

On April 14, 2021, Sysmex obtained *in vitro* diagnostic approval for the manufacturing and marketing of the DetectAmp SARS-CoV-2 RT-PCR Kit, a SARS coronavirus nucleic acid kit that detects the RNA of SARS-CoV-2 contained in nasopharyngeal swabs, nasal swabs, saliva, etc. The company also received insurance coverage for the kit on the same date. Using an enzyme that supports high-speed PCR testing, this product can complete the entire process from amplification of SARS-CoV-2 RNA to delivery of test results in about 40 minutes, detecting SARS-CoV-2 RNA with high sensitivity—at a minimum detection sensitivity of 8 copies per test (evaluated with a CLSI[3]-compliant test method).
For the main raw materials and container, this product is designed to use components procured in Japan. We will start by producing kits for 200,000 tests monthly, gradually boosting this production level over time. By building a self-sufficient production system in Japan, we will ensure a stable supply of high-quality products that will be unaffected by global supply shortages of raw materials, even in the event of future pandemics.
Furthermore, by utilizing this product combined with a fully automated system that incorporates a robot, a system which Sysmex commercialized with Kawasaki Heavy Industries, Ltd. and Medicaroid Corporation, we will conduct up to 1,250 tests per 8 hours.
By using a sample inactivating solution and an RNA extraction kit (both sold separately), we will also work to eliminate the need for virus inactivation and create a test flow that can employ common modes of transportation, thereby ensuring the safety of people directly involved in COVID-19 testing, such as medical professionals, and those involved in sample transport.

Basic experiments have confirmed that this product is theoretically capable of detecting the UK, South African, and Brazilian variants;[4] we plan to verify its performance using clinical samples going forward.

Sysmex remains committed to creating tests that are easier on patients, that reduce the risk of infection among medical professionals, and improve overall testing efficiency. We will also help to provide people with safe medical care and health benefits by increasing the number of tests available. We will do this by ensuring a stable supply of reagents and supporting automated testing.

Product Overview

JMDN:	SARS-CoV-2 Nucleic Acid Detection Kit (84014000)
Product name:	DetectAmp SARS-CoV-2 RT-PCR Kit (*in vitro* diagnostic medical device registration number: 30300EZX00036000)
Target market:	Japan
Marketing authorization holder:	Sysmex Corporation
Date of launch:	End of April 2021 (expected)
Applicable instruments:	Applied Biosystems 7500 Fast Dx (from Thermo Fisher Scientific, *in vitro* diagnostic medical device registration number: 13B1X10227000001) or its equivalent genetic analyzer

Overview of Insurance Coverage

Category:	D023 (microbial nucleic acid identification/quantitative test)
Parameter:	SARS-CoV-2 nucleic acid detection
NHI points:	SARS coronavirus nucleic acid detection 450 points x 4 = 1,800 points Category B (no infectious substances transported) 450 points x 3 = 1,350 points

Notes

1 Ministry of Health, Labour and Welfare's website "Basic Policies for Novel Coronavirus Disease Control" COVID-19 Situation in Japan, etc.
https://www.mhlw.go.jp/stf/covid-19/kokunainohasseijoukyou.html (Japanese only)

2 Japan Medical Association COVID-19 Experts' Meeting's Interim Report on PCR Test Field Survey and Test Promotion Task Force for COVID-19 Infection Control
https://www.covid19-jma-medical-expert-meeting.jp/topic/1310 (Japanese only)

3 CLSI:
The guidelines of the Clinical and Laboratory Standards Institution of the United States, which are accepted as a global standard

4 Variants:
UK variant: VOC-202012/01; South African variant: 501Y.V2; Brazilian variant: 501Y.V3