News Release

June 9, 2020
Sysmex Corporation

The Use of Saliva in PCR Tests for the Novel Coronavirus
- Expanding the Scope of Sample Types -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) has obtained the first marketing approval ("regulatory approval") in Japan for an in vitro diagnostic medical device, a testing kit for the novel coronavirus (2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit). We subsequently filed a change request, which was approved on June 2, 2020, additionally including saliva as a sample type. In line with a Ministry of Health, Labour and Welfare notification of the same date, the use of saliva was also included in health insurance coverage.

Compared with the previous method of sampling mucus from deep in the nose and throat, the taking of saliva samples is expected to be a safer, faster and simpler way to conduct PCR tests for the novel coronavirus.

On June 2, 2020, the Ministry of Health, Labour and Welfare announced that saliva obtained within nine days of the onset of symptoms could be used for PCR testing for the novel coronavirus, in addition to samples from the upper respiratory tract (nasopharyngeal swabs) and samples from the lower respiratory tract (sputum or alveolar fluid).

Expanding the PCR testing structure, various regional government bodies and medical societies have been working to accelerate sampling and reduce infection risk to medical professionals. One such approach has been the introduction of drive-through testing.

To date, testing has involved taking mucus samples from deep in the nose and throat, which places a burden on the person undergoing testing. Such testing may also prompt coughing or sneezing, leading to the droplet infection of the medical professionals performing the tests. Furthermore, use of goggles, face shields and other protective equipment has been necessary to prevent infection.

The introduction of PCR testing that uses saliva allows people undergoing testing to provide samples themselves, helping to make PCR testing for the novel coronavirus safer, faster, and simpler.

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 an equivalent genetic analyzer

Reference

News release dated March 27, 2020: “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”
https://www.sysmex.co.jp/en/news/2020/pdf/200327.pdf

News announcement by the Ministry of Health, Labour and Welfare (Japanese only): “Introduction of PCR Testing That Uses Saliva”
https://www.mhlw.go.jp/stf/newpage_11636.html

National Institute of Infectious Diseases report (Japanese only): “Manual for Taking and Transmitting Samples from Patients Suspected of 2019-nCoV (New Coronavirus), June 2, 2020 Update”
https://www.mhlw.go.jp/content/000635965.pdf

Ministry of Health, Labour and Welfare Contact Office notice (Japanese only): “The Handling of Testing Fee Points”
https://www.mhlw.go.jp/content/000636341.pdf

Ministry of Health, Labour and Welfare Contact Office notice (Japanese only): “The Sending of Interrogative Material (No. 15)”
https://www.mhlw.go.jp/content/000636345.pdf