September 29, 2020
Sysmex Corporation

Sysmex Applies for Manufacturing and Marketing Approval for a SARS-CoV-2 Antigen Detection Reagent

- Detecting SARS-CoV-2 Antigens Using Fully Automated Immunoassay Systems HISCL™-5000 / HISCL™-800 -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced today that on September 29, 2020, it applied for *in vitro* diagnostic approval for manufacturing and marketing of a reagent for detecting antigens of SARS-CoV-2 (the "Reagent"), which causes coronavirus disease 2019 (COVID-19), in conjunction with its fully automated immunoassay systems HISCL™-5000 / HISCL™-800 to the Pharmaceuticals and Medical Devices Agency (PMDA).

The Reagent detects SARS-CoV-2 antigens present in nasopharyngeal swabs. When used in conjunction with Sysmex's fully automated immunoassay systems HISCL™-5000 / HISCL™-800, which use chemiluminescence enzyme immunoassay (CLEIA) as their measurement principles, it not only performs measurement with high sensitivity but also improves testing efficiency by delivering rapid test results in 17 minutes from the start of testing and processing 200 tests per hour (with HISCL™-5000). Additionally, SARS-CoV-2 present in samples is deactivated after nasopharyngeal swab collection by using a sample extraction solution (sold separately), thus reducing the infection risk to medical professionals.

To prepare for the surge in testing demand anticipated after manufacturing and marketing approval, we are working to reinforce supply systems for a stable supply of the Reagent and fully automated immunoassay systems.

We are also considering expanding the scope of sample types to reduce both the physical burden on patients and the infection risk to medical professionals at the time of sampling.

Sysmex will remain committed to the establishment of diagnosis/treatment methods for COVID-19 by way of diverse testing techniques, including PCR tests, antigen tests, antibody tests, and cytokine tests, as well as existing ones such as hematology and coagulation tests.