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News Release

November 11, 2020
Sysmex Corporation

Sysmex Obtains 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 Ietusgu) announced today that on November 10, 2020, it obtained *in vitro* diagnostic approval for manufacturing and marketing of a SARS coronavirus antigen kit HISCL™ SARS-CoV-2 Ag Reagent, which, in conjunction with its fully automated immunoassay systems HISCL™-5000 / HISCL™-800, is capable of detecting antigens of SARS-CoV-2, the strain of coronavirus that causes COVID-19, and that the kit received insurance coverage on November 10, 2020.

Now that regulatory approval and insurance coverage have been granted, we will launch the product on November 18, 2020.

In accord with "Institutional Enhancement of Preparedness for the Next Influenza Season," an Office Memorandum released by the Novel Coronavirus Response Headquarters of the Ministry of Health, Labour and Welfare of Japan on September 4, 2020, concerted efforts are being made by the national and local governments to expand the coronavirus testing capacity under the Guidelines for Enhancement of the COVID-19 Testing System.

In an attempt to make COVID-19 testing accessible to more people by providing medical professionals with *in vitro* diagnostic products for SARS-CoV-2, Sysmex has obtained the first regulatory approval in Japan for a PCR testing kit and also applied for *in vitro* diagnostic approval for manufacturing and marketing of a SARS-CoV-2 antigen detection reagent to the Pharmaceuticals and Medical Devices Agency (PMDA) on September 29, 2020.

On November 10, 2020, Sysmex received the regulatory approval for its SARS coronavirus antigen kit HISCL™ SARS-CoV-2 Ag Reagent, which received insurance coverage on November 10, 2020. Accordingly, Sysmex will launch the kit on November 18, 2020. When used in conjunction with Sysmex's fully automated immunoassay systems HISCL™-5000 / HISCL™-800 (medical devices that use chemiluminescence enzyme immunoassay [CLEIA] as their measurement principles), the kit not only provides highly reliable detection results of SARS-CoV-2 antigens in samples from nasopharyngeal swabs and nasal swabs but also improves testing efficiency by delivering rapid test results in 17 minutes and can process 200 tests per hour (with HISCL™-5000). Additionally, Sysmex offers a sample extraction solution (sold separately), which deactivates SARS-CoV-2 present in nasopharyngeal/nasal swabs, thus reducing the infection risk to medical professionals.

Sysmex will remain committed to establishing 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 procedures such as hematology and coagulation tests.

Product Overview

Generic name:	SARS coronavirus antigen kit (84110000)
Brand name:	HISCL™ SARS-CoV-2 Ag Reagent (*in vitro* diagnostic medical device registration number: 30200EZX00078000)
Target market:	Japan
Manufactured/marketed by:	Sysmex Corporation

Details of Insurance Coverage

Classification:	D012 (Immunological Tests for Infectious Diseases)
Item of measurement:	Detection of SARS-CoV-2 antigens
NHI points:	600
Points to consider:	Points for detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens shall be calculated by applying specified points that are the aggregate of four lots of "25. Mycoplasma antigen (Qualitative) (Immunochromatography method)," in a procedure diagnosing COVID-19 (coronavirus disease 2019) in suspected carriers. This assumes the procedure is performed by a party who has obtained regulatory approval or certification, and by using samples collected in the same manner employed when regulatory approval was granted to the test kit in question for the detection of SARS-CoV-2 antigens (to diagnose or assist diagnosis of COVID-19). However, the points may not be assigned if a test is performed for the sake of active epidemiological investigation to elucidate the occurrence, trends, and causes of an infectious disease. When this test has been performed for diagnostic purpose on those suspected of having COVID-19, the points thus aggregated above shall be assigned only once before the diagnosis is confirmed. If a patient tests negative for COVID-19 after symptoms develop but a diagnosis for something other than COVID-19 remains unmade, the points thus aggregated above may be assigned one last time. Medical evidence for the decision that this test is necessary shall be provided in the space for notes on a statement of medical expenses.