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News Release

February 19, 2021
Sysmex Corporation

Sysmex Obtains Manufacturing and Marketing Approval for an Influenza A/B Virus Antigen Detection Test Kit

- Influenza can be simultaneously measured in a short period of time in the same the novel coronavirus (SARS-CoV-2) antigen sample using the HISCL™-5000/HISCL-800 Automated Immunoassay Systems -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced today that on February 18, 2021, it obtained *in vitro* diagnostic approval for the manufacturing and marketing of the HISCL Influenza Assay Kit, which is capable of detecting influenza A and B virus antigens individually. In addition, the kit received insurance coverage on February 18, 2021.
The combined use of this kit and the SARS coronavirus antigen kit HISCL SARS-CoV-2 Ag Reagent,[1] in conjunction with the HISCL-5000 / HISCL-800 automated immunoassay systems, will make it possible to simultaneously measure antigens of influenza viruses and SARS-CoV-2 using a single sample,[2] which will reduce the burden on both medical professionals and patients.

In accordance with the "Institutional Enhancement of Preparedness for the Next Influenza Season" and "Guidelines for Enhancement of the COVID-19 Testing System" Office Memorandums released by the Novel Coronavirus Response Headquarters of the Ministry of Health, Labour and Welfare of Japan on September 4 and 15, 2020, respectively, the national and local governments are making concerted efforts to enhance and expand coronavirus testing capacity.
On February 18, 2021, Sysmex obtained manufacturing and marketing approval for the HISCL Influenza Assay Kit and received insurance coverage for it. This product is capable of individually detecting influenza A and B virus antigens in samples. When used in conjunction with Sysmex's HISCL-5000/HISCL-800 automated immunoassay systems, which use chemiluminescence enzyme immunoassay (CLEIA) as their measurement principle, this new kit not only provides highly reliable detection results but also improves testing efficiency by delivering results in 17 minutes and processing 200 tests per hour (with the HISCL-5000).
The combined use of this product and the HISCL SARS-CoV-2 Ag Reagent will make it possible to simultaneously measure antigens of influenza A and B viruses and SARS-CoV-2 using a single sample, which will reduce the burden on both medical professionals and patients and contribute to prompt and appropriate treatment for patients with fever and respiratory symptoms. Sysmex also offers a sample extraction solution (sold separately), which reduces infection risk by making it possible for medical professionals to inactivate influenza viruses and SARS-CoV-2 that might be present in samples.

Sysmex will remain committed to reducing the burden on patients and the infection risk to medical professionals, as well as increasing testing efficiency.

Product Overview

Generic name:	Influenza Virus Kit
Product name:	HISCL Influenza Assay Kit (*in vitro* diagnostic medical device registration number:30300EZX00018000)
Target market:	Japan
Manufacturer and seller:	Sysmex Corporation
Launch:	End of February 2021 (expected)

Details of Insurance Coverage

Classification:	D012 (Immunological Tests for Infectious Diseases)
Item of measurement:	Influenza virus antigens (Qualitative)
NHI points:	139

Notes

1 SARS coronavirus antigen kit HISCL SARS-CoV-2 Ag Reagent:
In vitro diagnostic medical device registration number: 30200EZX00078000
Manufacturer and seller: Sysmex Corporation
November 11, 2020 news release: “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 -”
https://www.sysmex.co.jp/en/news/2020/pdf/201111.pdf

2 Sample:
Refers to nasopharyngeal or nasal swabs for the purpose of this release