News Release

February 12, 2021
Sysmex Corporation

Insurance Coverage Received for HISCL™ IFN-λ3 Assay Kit, a Test Kit to Assist in Determining Exacerbation Risk in SARS-CoV-2-Positive Patients

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announced today that it has received approval for insurance coverage for the HISCL IFN-λ3 Assay Kit, an interferon-λ3 kit for which marketing approval was obtained on December 22, 2020, as a test kit to assist in determining the exacerbation risk in novel coronavirus (SARS-CoV-2)-positive patients. The coverage went into effect on February 3, 2021.
As insurance coverage should provide more COVID-19 patients with access to this test, it is expected that patients with exacerbation risks will be able to receive appropriate treatment, and that a new treatment guideline will be established.

It is reported that about 10% of COVID-19 patients develop severe symptoms that require oxygen inhalation or ventilators.[1] Also, some patients reportedly have a characteristic clinical course in which they experience seemingly mild symptoms in the early stages of the disease, but then rapidly deteriorate to become critically ill. As the number of new COVID-19 cases continues to soar in Japan, medical institutions are finding it increasingly difficult to accommodate patients, with the result that a rising number of people are forced to stay at home during recovery. This being the case, it is believed that identifying patients with exacerbation risks at an early stage will not only increase the potential to save their lives, but also allow for an adequate allocation of limited healthcare resources.

Through joint research, Sysmex and the National Center for Global Health and Medicine have identified that the blood level of IFN-λ3 increase rapidly several days before severe symptoms become apparent.[2,3] Accordingly, Sysmex has developed an interferon-λ3 kit, the HISCL IFN-λ3 Assay Kit, a novel *in vitro* diagnostic product that assists in determining the exacerbation risk in SARS-CoV-2-positive patients, and obtained marketing approval for it on December 22, 2020.[4]
On February 3, 2021, Sysmex received insurance coverage for the HISCL IFN-λ3 Assay Kit as a test kit that assists in the determination of exacerbation risks in COVID-19 patients.[5]
What this means is that it will be easier for medical professionals to periodically measure IFN-λ3 in serum for patients that have tested positive for COVID-19 with mild symptoms (fatigue, cough, fever) or moderate symptoms (shortness of breath, early signs of respiratory disorders).
As more COVID-19 patients have access to this test as part of insurance-covered treatment, it will become possible to plan the course of therapy earlier, allocate healthcare resources based on that plan, and facilitate the appropriate management of conditions and treatment of patients who are running a higher risk of exacerbation.
Furthermore, as more research is conducted and further treatment guidelines are developed, it is expected that the clinical usefulness of advising patients to receive treatment in hospitals or providing them with early treatment will be established.

Going forward, Sysmex will remain committed to conducting research into COVID-19 and establishing diagnosis and treatment by creating high-value-added testing and diagnostic technologies and providing patients with expanded access to this insurance-covered test.

Product Overview

Generic name:	Interferon-λ3 Kit
Product name:	HISCL IFN-λ3 Assay Kit (*In vitro* diagnostic medical device registration number: 30200EZX00089000)
Intended use:	Measurement of IFN-λ3 in serum (to assist in determining the exacerbation risks of SARS-CoV-2-positive patients)
Target market:	Japan
Manufacturer and seller:	Sysmex Corporation
Launch:	January 5, 2021

Details of Insurance Coverage[5]

Classification for application:	E3 (New item)
Item of measurement:	Interferon-λ3 (IFN-λ3)
Measurement method:	Chemiluminescence enzyme immunoassay using a two-step sandwich method
NHI points:	340
Points to consider:	(10) Interferon-λ3 (IFN-λ3) a. When measuring interferon-λ3 (IFN-λ3) with an chemiluminescence enzyme-linked immunoassay using a two-step sandwich method for the purpose of assisting in determining the exacerbation risk in COVID-19 patients (excluding patients with severe or critical symptoms requiring management of respiratory failure), points shall be calculated by applying the specified points for "14. Evaluation of Hepatitis B Virus Genotyping" of "D013 (Hepatitis Virus-Related Tests)." b. When calculating points for two or more applications of this test, it shall be confirmed that the results of the previous test are below the cut-off. c. When points are calculated for this test by applying specified points for "14. Evaluation of Hepatitis B Virus Genotyping" of "D013 (Hepatitis Virus-Related Tests)", the provisions in the "Notes" to "D013 (Hepatitis Virus-Related Tests)" shall not be applicable.

Notes

1 Coronavirus Diseases 2019 (COVID-19) Treatment Guidelines, 4th edition (issued on December 4, 2020)

2 Sugiyama M. *et al*., Gene 766, (2021) 145145

3 National Center for Global Health and Medicine. “Identification of humoral factors that predict exacerbation of COVID-19: Seeking the early diagnosis of COVID-19 by blood test.” September 24, 2020
http://www.ncgm.go.jp/pressrelease/2020/20200924.html (Japanese only)
4 December 23, 2020 news release “Sysmex Obtains Marketing Approval for the HISCL™ IFN-λ3 Assay Kit, a Test Kit to Assist in Determining Exacerbation Risk in Novel Coronavirus (SARS-CoV-2)-Positive Patients”
https://www.sysmex.co.jp/en/news/2020/pdf/201223.pdf
5 Calculation of points for testing fees (February 3, 2021 保医発 0203 第 2 号)
