News Release

December 23, 2020
Sysmex Corporation

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

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) obtained marketing approval on December 22, 2020 for the HISCL IFN-λ3 reagent, an interferon-λ3 kit.
The new product can be used in combination with the HISCL-5000/HISCL-800 Automated Immunoassay Systems to measure the serum level of interferon-λ3 (IFN-λ3) to provide information to assist in determining the exacerbation risk in SARS-CoV-2-positive patients.

Respiratory infections are diseases caused by pathogens infecting the respiratory system including the nasal cavity, pharynx, trachea, bronchi, and alveoli. These pathogens include viruses, bacteria, fungi, and parasites; the viruses include coronaviruses and influenza.
It has been reported that patients infected with SARS-CoV-2 experience cold symptoms, such as fever, as well as symptoms of respiratory infection, such as dysgeusia and dysosmia. Ninety percent of patients recover and experience mild or moderate symptoms, whereas 10% develop severe symptoms that require oxygen inhalation or ventilators.[1] Severely affected patients have a characteristic clinical course in which they experience seemingly mild symptoms in the early stages of the disease, but then rapidly worsen to the point where oxygen ventilators are required.

Through joint research, Sysmex and the National Center for Global Health and Medicine have identified IFN-λ3, which is a useful biomarker for discriminating patients who are at high risk of worsening symptoms. It has been found that the blood level of IFN-λ3 rises rapidly several days before severe symptoms become apparent. IFN-λ3 has also been reported to be clinically useful for predicting the onset of severe symptoms resulting from the novel coronavirus disease (COVID-19) and for assisting with follow-up.[2,3]

On December 22, 2020, Sysmex obtained marketing approval for the interferon-λ3 kit, the HISCL IFN-λ3 Assay Kit. This product can be used in combination with HISCL-5000/HISCL-800 Automated Immunoassay Systems to measure IFN-λ3 in serum, and thereby assist in determining the exacerbation risk in SARS-CoV-2-positive patients. A rapid reaction time of 17 minutes and an hourly throughput of 200 tests (in the case of HISCL-5000) ensure fast and efficient testing.

In clinical settings, being able to predict if a condition is likely to become more severe helps doctors focus on providing the most comprehensive treatment for high-risk patients. This means that limited medical resources can be allocated more efficiently, leading to a reduction in the psychological stress not only on patients and their families, but also on healthcare professionals.

Development of therapies which utilize the IFN-λ3 test results of patients under treatment as an indicator of exacerbation will, if successful, help to reduce disease severity and mortality, making

more effective treatment a feasible prospect in the future.

Sysmex will contribute to research on COVID-19 and the establishment of its diagnosis and treatment through a variety of tests, including PCR, antigen, antibody, and cytokine tests, as well as existing hematology and hemostasis tests. We will also continue to investigate the clinical usefulness of other promising biomarkers.

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 (Assist in determining the exacerbation risk of SARS-CoV-2-positive patients)
Target market:	Japan
Manufacturer and seller:	Sysmex Corporation
Launch:	January 2021 (expected)

References

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)