

June 7, 2021  
Sysmex Corporation  
Shionogi & Co., Ltd

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## Th2 Chemokine TARC Kit "HISCL™ TARC Assay Kit" is Approved for an Additional Indication as an Auxiliary for Assessment of COVID-19 Aggravation risk

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Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D. ; hereafter "Shionogi") and Sysmex Corporation (Head Office: Hyogo, Japan; Chairman & CEO: Hisashi Ietsugu; hereinafter "Sysmex") announced that HISCL TARC Assay Kit, a Th2 chemokine (TARC) kit (hereinafter "the test kit"), was approved on June 7 for an additional indication<sup>1</sup> as an auxiliary for assessment of aggravation risk in patients who have tested positive for SARS-CoV-2. The kit was developed jointly by the two companies in 2014.

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COVID-19 is a disease that can rapidly become more severe even if early symptoms are mild. Due to difficulties determining the progression of symptoms, continuous observation and treatments are required at medical institutions and other facilities. Therefore, the society recognizes the necessity to relieve a medical system overwhelmed by an increasing number of people receiving medical treatment at these facilities, and an increase in patients with severe symptoms, in order to reduce the risk of a future medical collapse.

The test kit enables easy determination of TARC, a type of chemokine (systematic element name: CCL17), using Sysmex's Automated Immunoassay System HISCL-5000/HISCL-800. Through the latest clinical research, the National Center for Global Health and Medicine has identified TARC, which is a useful biomarker for predicting the aggravation of COVID-19 patients from an early stage with a single measurement<sup>2</sup>. It has been confirmed that the serum level of TARC remain low value in patients with severe symptoms of COVID-19 from early onset to aggravation.

Sysmex's interferon-λ3 kit "HISCL IFN-λ3 Assay Kit"<sup>3</sup>, which was insured on February 3, 2021, is a kit used to predict aggravation of COVID-19. It is mainly used for the purpose of early detection of signs of aggravation in inpatients. With the approval of this additional indication for "HISCL TARC Assay Kit", a new diagnostic method useful for predicting the aggravation risks of SARS-CoV-2 positive patients will be added. Assessment of aggravation risk in the initial stage of onset can lead to optimal measures in an individual manner, such as inpatient treatment for those at high risk and hotel quarantine or at-home treatment for low-risk patients. Through the provision of both test kits, Shionogi and Sysmex will contribute to the preparation of appropriate treatment in the medical field and the optimization of medical resources, from both risk assessment and monitoring of signs of aggravation for SARS-CoV-2 positive patients.

## About TARC

TARC (thymus and activation-regulated chemokine) is a protein composed of 71 amino acids and is one of the chemokine group that migrates Th2 cells, which are one of the lymphocytes, to the inflamed site. It is suggested that an abnormal immune balance between Th1 cells and Th2 cells<sup>4,5</sup> may be involved in the aggravation of COVID-19.

## About HISCL TARC Assay Kit

HISCL TARC Assay Kit is a test kit which enables easy determination of TARC using the principle of Chemiluminescent Enzyme Immunoassay (CLEIA). It has been used as an in-vitro diagnostic reagent for supporting severity assessment of atopic dermatitis.

## About HISCL IFN- $\lambda$ 3 Assay Kit

HISCL IFN- $\lambda$ 3 Assay Kit is a test kit which enables determination of interferon  $\lambda$ 3 ("IFN- $\lambda$ 3"). Joint research by Sysmex and the National Center for Global Health and Medicine has confirmed that rapid elevation of IFN- $\lambda$ 3 levels in blood is seen a few days before symptoms become severe. On December 22, 2020, Sysmex acquired marketing authorization for the product as a novel in-vitro diagnostic kit to assist in determining the aggravation risks of SARS-CoV-2, and the kit has been covered by national health insurance<sup>3</sup> since February 3, 2021.

## Product Overview

Generic name:	Th2 Chemokine TARC Kit
Product name:	HISCL™ TARC Assay Kit (Registration number:225AAAMX00132000)
Target market:	Japan
Intended use:	For measuring the amount of human TARC in serum (to assist in determining the exacerbation risks of SARS-CoV-2-positive patients, to assist in determining the severity of atopic dermatitis)
Approval obtained:	June 7, 2021 (for an additional indication)
Measurement method:	Chemiluminescent enzyme immunoassay (CLEIA) method
Measurement response time:	17 minutes
NHI points:	Application in progress
Manufacturer and seller:	Shionogi & Co., Ltd
Seller:	Sysmex Corporation
Appearance:	



### **About Sysmex Corporation**

In line with its mission of “shaping the advancement of healthcare,” which is defined in the “Sysmex Way,” the corporate philosophy of the Sysmex Group, Sysmex works to contribute to the development of healthcare and the healthy lives of people. Sysmex conducts integrated R&D, manufacturing and sales, and provides support services for its instruments, reagents and software for in vitro testing of blood, urine and other bodily fluids. Sysmex supplies its products to medical institutions in more than 190 countries and regions throughout the world. In recent years, Sysmex has been expanding its business in the life science domain, using proprietary technologies to create new testing and diagnostic value, realize healthcare that is optimized for individual patients, and help reduce patients’ burdens and enhance their quality of life.

URL : <https://www.sysmex.co.jp/en/index.html>

### **About Shionogi & Co., Ltd**

Shionogi is committed to “Protecting people worldwide from the threat of infectious diseases” as our key focus. In addition to our continued efforts for the research and development of therapeutics, we are also pursuing total care for infectious diseases, through awareness building, prevention, diagnosis, and treatment of exacerbations, as well as addressing the infection itself. We will continue to strive to fulfill our social responsibility and seek to contribute to re-establishing the safety and security of society by bringing forward new tools and technologies for the prevention, diagnosis, and treatment of COVID-19 to support early containment of the pandemic.

URL : <https://www.shionogi.com/global/en/>

### **Reference**

- 1 [Press release on April 26, 2021:](#)  
Shionogi Filed the Application for Marketing Approval of Th2 Chemokine TARC Kit "HISCL<sup>®</sup> TARC reagent" to Assist in Predicting the Exacerbation of COVID-19
- 2 [NGCM updated information on Sept. 24, 2020:](#)  
Identification of liquid factor predicting aggravation of COVID-19 – Aiming at early diagnosis of COVID-19 with blood test
- 3 [Press release on Feb. 12, 2021:](#)  
Insurance Coverage Received for HISCL<sup>™</sup> IFN-λ3 Assay Kit, a Test Kit to Assist in Determining Exacerbation Risk in SARS-CoV-2-Positive Patients
- 4 Int Immunol. 1999, 11:81-88.
- 5 FASEB J. 1991, 5:171-177.

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The purpose of this press release is to communicate our business activities to our stakeholders. It may or may not include information about Sysmex's products or their research and development, but this is not intended for promotion, advertising or medical advice. The information contained in the press release is current as of the date of this announcement but may be subject to change without prior notice.