

July 3, 2020  
Sysmex Corporation

## Sysmex to Launch Novel Coronavirus (SARS-CoV-2) Antibody Lab Assay Service and Antibody Measurement Reagents (for Research)

- Using the HISCL™-5000/HISCL™-800 Fully Automated Immunoassay Systems  
to Realize SARS-CoV-2 Antibody Detection -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) has established four antibody measurement technologies that enable detection of the circulating IgG antibody<sup>1</sup> and IgM antibody.<sup>2</sup> These antibodies react specifically to the nucleocapsid protein<sup>3</sup> (N antigen) and spike protein<sup>4</sup> (S antigen) in SARS-CoV-2, the virus that causes the novel coronavirus (COVID-19). From June 12, 2020, we began sequentially providing lab assay services. Furthermore, on July 22, 2020 we plan to launch antibody measurement reagents (for research) for use with the HISCL™-5000/HISCL™-800 fully automated immunoassay systems.

Currently, the first infectious wave of COVID-19 is converging in Japan, but the infection spread of the successively second wave, the third wave is expected. In preparation for the expected resurgence of COVID-19, we recognize the urgent need to establish a new testing methodology effective throughout from immediately after infection to the treatment and recovery period.

We believe SARS-CoV-2 antibody tests can be used to determine the past history of SARS-CoV-2, and in diagnostic technologies related to neutralizing activity and other defensive functions. They may also be used for drug discovery research on vaccines to prevent the disease, and on antiviral drugs for treatment, as well as for setting activity standards related to economic activity and immigration control.

Sysmex has developed four antibody measurement reagents for research related to SARS-CoV-2: the HISCL™ SARS-CoV-2 N-IgG reagent (for research), the HISCL™ SARS-CoV-2 S-IgG reagent (for research), the HISCL™ SARS-CoV-2 N-IgM reagent (for research) and the HISCL™ SARS-CoV-2 S-IgM reagent (for research).

These detection reagents can be used in combination with Sysmex's fully automated immunoassay systems, the HISCL™-5000/ HISCL™-800, to detect individual antibodies (IgG and IgM antibodies) that react specifically with the N antigen and the S antigen. These reagents have been used in a clinical performance evaluation using IgG antibody detection. They were used to compare concentrations of IgG antibodies with respect to circulating N antigens and S antigens between a SARS-CoV-2 negative group and a group of SARS-CoV-2 patients upon hospital discharge. The evaluation indicated a rise in the amount of antibody in the patient group, obtaining clearly discriminating performance from the negative group. Such results suggest that going forward, the reagents might be used for research into the past history COVID-19 and research and consideration of the clinical significance of the SARS-CoV-2 defense function, as well as in a host of epidemiological studies. [https://www.sysmex.co.jp/en/news/2020/pdf/200703\\_01.pdf](https://www.sysmex.co.jp/en/news/2020/pdf/200703_01.pdf)

On June 12, 2020, Sysmex began the sequential launch of an antibody lab assay service to support research, measuring samples received by Sysmex's lab assay institutions and reporting results. On July 22, 2020, we also plan to launch antibody measurement reagents that can be used with the HISCL™-5000/ HISCL™-800 fully automated immunoassay systems.

Sysmex aims to contribute to the diagnosis and treatment of COVID-19 by helping with the accumulation of a wide range of clinical evidence related to COVID-19 including epidemiological studies, and the promotion of drug discovery and other research.

## Product Overview

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|----------------|---|
| Names:         | Antibody lab assay service (for research)<br>SARS-CoV-2 antibody measurement service (lab assay for research) |
|                | Antibody measurement reagents (for research)  |
|                | HISCL™ SARS-CoV-2 N-IgG reagent (for research)  |
|                | HISCL™ SARS-CoV-2 S-IgG reagent (for research)  |
|                | HISCL™ SARS-CoV-2 N-IgM reagent (for research)  |
|                | HISCL™ SARS-CoV-2 S-IgM reagent (for research)  |
| Target market: | Japan   |
| Launch date:   | Lab assay service: June 12, 2020<br>Reagent kit (for research): July 22, 2020 (anticipated)                   |

## Terminology

- 1 IgG antibody:  
One of the most prevalent circulating antibodies, which has a strong neutralizing effect.
- 2 IgM antibody:  
One of the first antibodies produced when a foreign substance enters the body, causing its level to increase for a certain period of time.
- 3 Nucleocapsid protein (N antigen):  
A protein that constitutes the core structure of a virus, significantly affecting virus characteristics.
- 4 Spike protein (S antigen):  
Protein that forms countless protrusions around the virus to bind with cell receptors and generate infection.