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Kobe University  
Sysmex Corporation

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## Kobe University and Sysmex Conducted Clinical Evaluation of the ELISPOT Method: A New Test for COVID-19 using blood

- Report on T cell Immunity to SARS-CoV-2 in the Japanese Population -

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Kobe University (Location: Kobe, Japan; President: Hiroshi Takeda) and Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) have been engaged in joint research on the ELISPOT method, a new blood test for identifying the novel coronavirus disease (COVID-19). This method makes it possible to detect the immune response of T cells to the novel coronavirus (SARS-CoV-2). Here we provide an overview of the method and the results of the clinical evaluation. This information will also be made available through conference presentations and by paper submission.

Although SARS-CoV-2 is highly infectious and may rapidly develop into a severe condition, many carriers of the virus are asymptomatic. To address this situation, research has been carried out to develop ways in which vaccine efficacy and safety can be assessed, in addition to the tests conducted in the period shortly after SARS-CoV-2 infection through to the treatment / recovery phase. “T-SPOT® Discovery SARS-CoV-2” (hereinafter referred to as the “kit”), the research reagent kit developed by Oxford Immunotec Ltd. (HQ: Oxford, the United Kingdom), measures the number of T cells that secrete interferon (IFN)  $\gamma$  by stimulating an infected SARS-CoV-2 specific antigen and can confirm past exposure to SARS-CoV-2 and latent infection. It will also enable research on immune monitoring and the strength of the immune response to COVID-19 (Figure 1).

Recently, the research group from Kobe University Hospital BioResource Center (Location: Kobe, Japan; Director: Hiroshi Matsuoka) and Sysmex used this kit to examine blood samples collected from 10 uninfected Japanese subjects and 15 Japanese subjects who had recovered from COVID-19. The results obtained so far show enhanced T cell immune responses in all individuals who recovered from COVID-19, while no enhanced T cell immune responses were found in uninfected individuals. This result suggests that the kit can be used to evaluate T cell immune response to SARS-CoV-2 in the Japanese population as well. It could also be utilized to complement PCR tests to measure gene expression, and antibody / antigen tests to measure the characteristics of proteins (Figure 2 and 3).

This kit has been selected by the Vaccines Taskforce established by the British government<sup>1</sup> and is used to evaluate vaccines' activation of immune functions. It may also provide important findings that will aid the development of future treatment strategies.

Sysmex and Kobe University will conduct further joint research at the molecular and cellular levels. Both parties will continue to contribute towards the diagnosis and treatment of COVID-19 by disclosing further details regarding T cell immunity and expeditiously establishing a test method suitable for clinical use.

The kit will be exclusively sold in Japan by Riken Genesis Co., Ltd., a subsidiary of Sysmex.<sup>2</sup>

[https://www.rikengenesis.jp/dcms\\_media/other/20201202\\_PressRelease\\_T-SPOT-discovery\\_RG\\_final.pdf](https://www.rikengenesis.jp/dcms_media/other/20201202_PressRelease_T-SPOT-discovery_RG_final.pdf) (Japanese only)

### Cascade of immune response to SARS-CoV-2 and tests to measure each substance

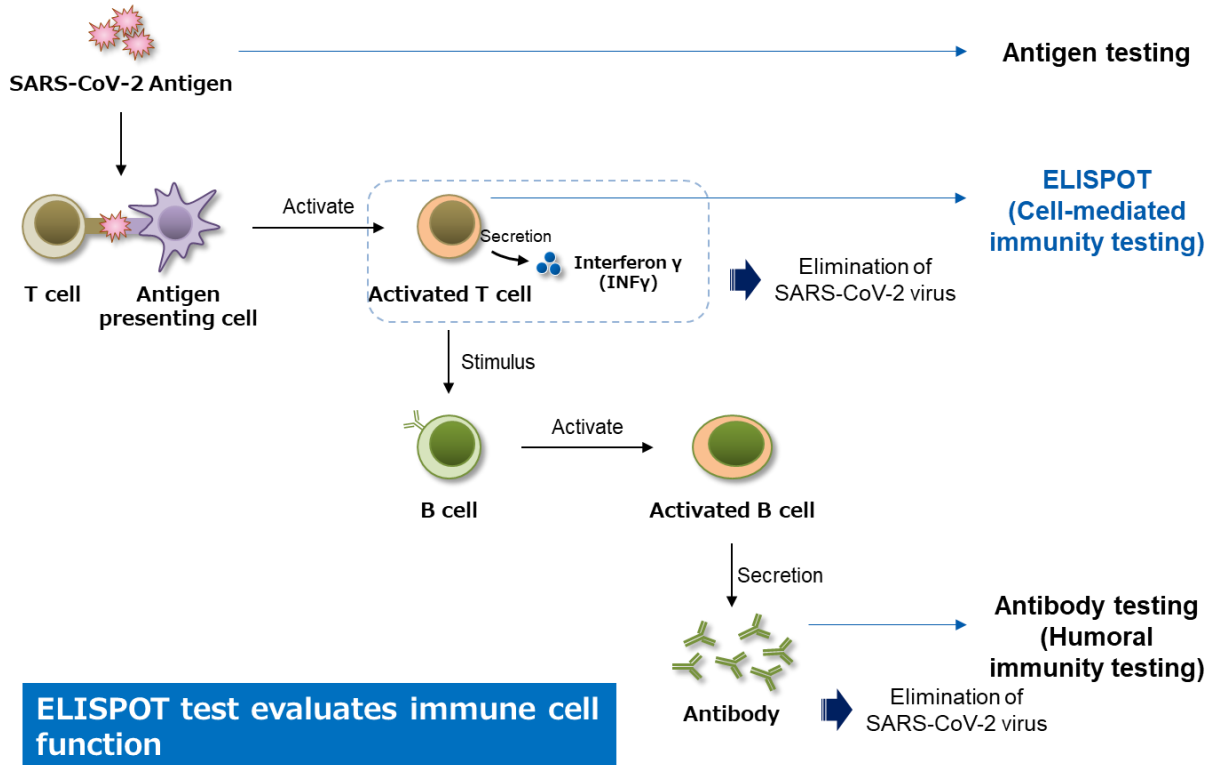
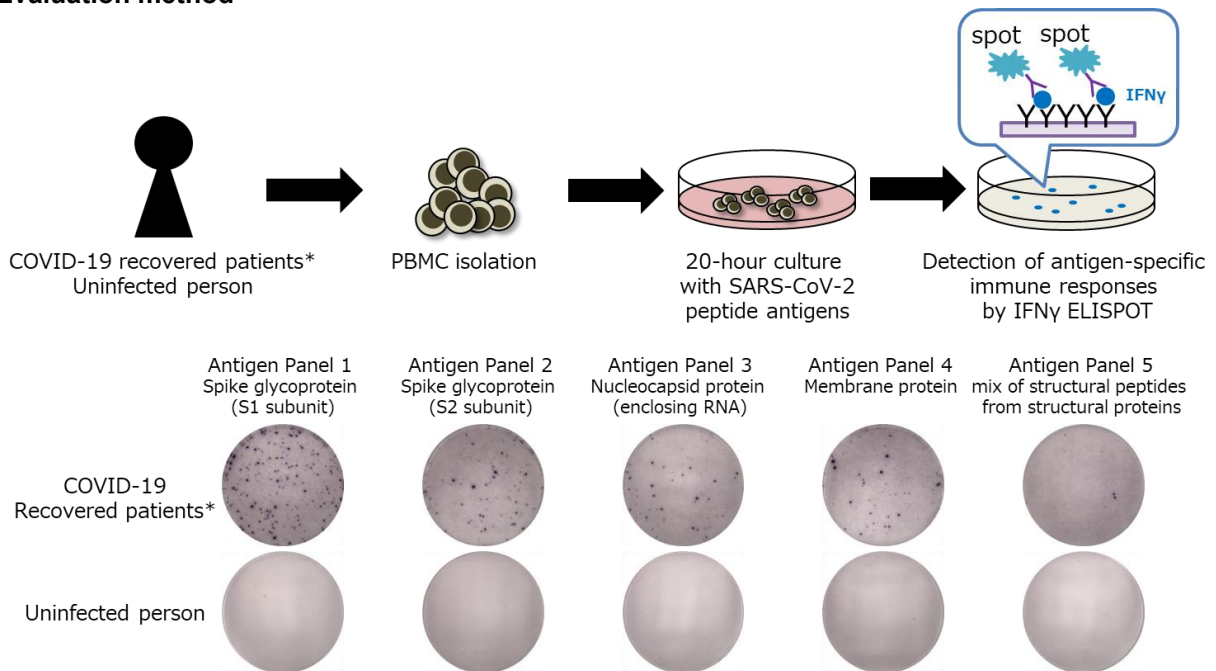


Figure 1. Cascade of immune response to SARS-CoV-2 and tests to measure each substance

### Evaluation method



\*COVID-19 recovered patients: Asymptomatic for >2 weeks after positive PCR result

Figure2. Sequence of the ELISPOT method and results of immune response detection

**Data on T cell immune response using the ELISPOT method**

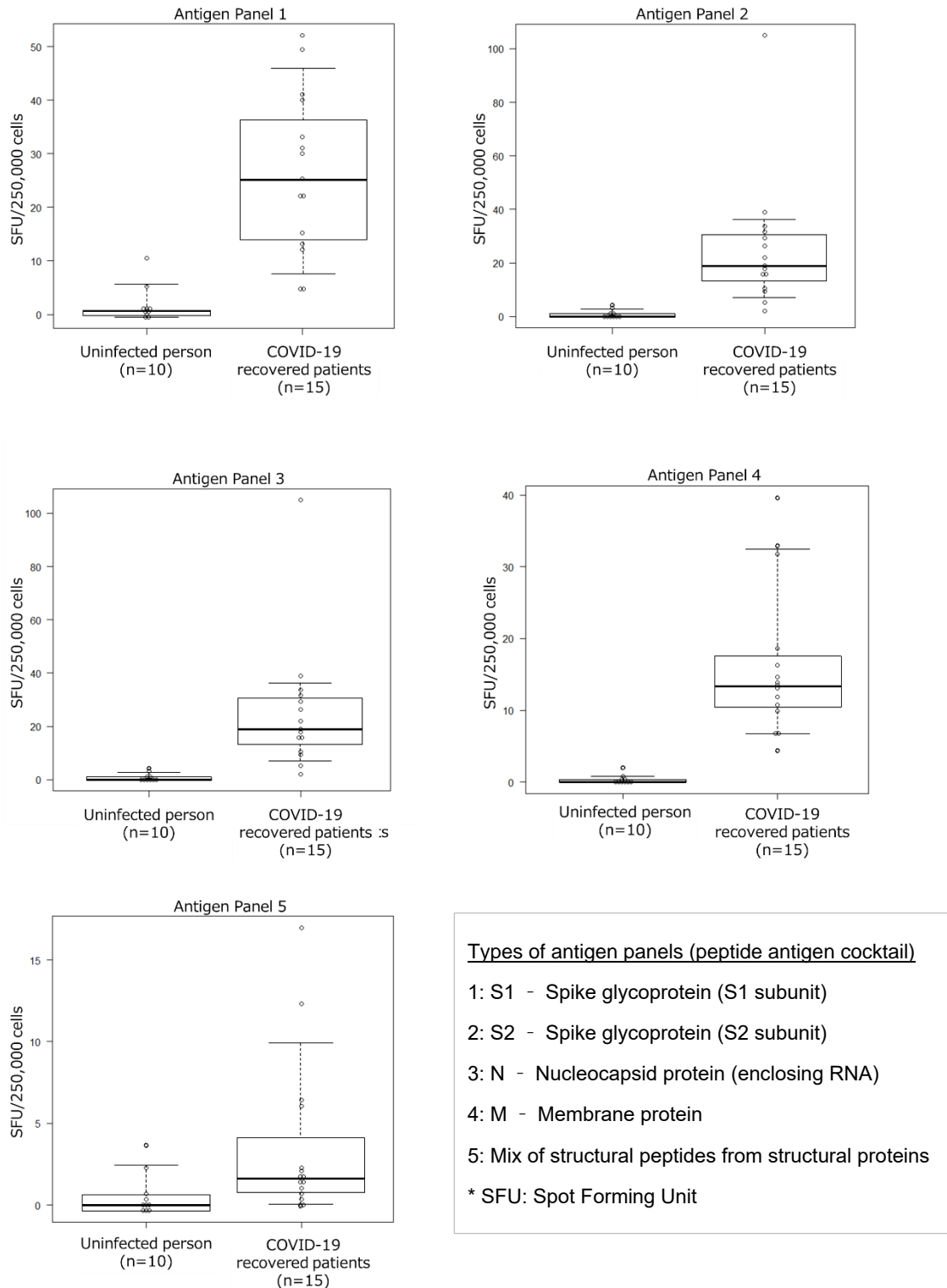


Figure 3. A statistically significant difference in the T cell immune response to antigen specific for SARS-CoV-2 between the Negative Group (n=10) and Positive Group (n=15) was confirmed

### **Kobe University's involvement in COVID-19 research**

Kobe University sees its mission as promoting research/studies to overcome the health risks and issues posed by COVID-19 and bringing its work to the attention of society. Based on this mission, researchers in both the arts and sciences have been engaged in various research undertakings and studies. The research outcomes published to date include the development of clean units and active masks, analysis of neutralizing antibodies and cytokine production in severely affected COVID-19 patients, and the establishment of a screening system so that drug discovery can be carried out safely. Additionally, researchers have been engaged in anti-COVID-19 measures: research outcomes resulted in being selected by the Japan Agency for Medical Research and Development (AMED) for "development of a vaccine against novel coronavirus infection (COVID-19)." They have also been involved in basic research on the development of biosensors that can detect intact SARS-CoV-2 with high specificity / high sensitivity. This was also adopted by AMED as part of the "technology development project for combating infectious diseases (basic research support)."

In addition, Kobe University has been actively contributing to society through such avenues as its "Kobe University 'With COVID-19' symposium: Considering how society can coexist with novel coronavirus" held in July 2020.

[https://www.kobe-u.ac.jp/en/NEWS/info/2020\\_07\\_30\\_01.html](https://www.kobe-u.ac.jp/en/NEWS/info/2020_07_30_01.html)

[https://www.kobe-u.ac.jp/NEWS/info/covid19\\_research.html](https://www.kobe-u.ac.jp/NEWS/info/covid19_research.html) (Japanese only)

### **Sysmex's involvement in COVID-19 research**

Sysmex, a provider of *in vitro* diagnostic instruments and reagents, believes that it is our mission to support the medical professionals who are on the frontline of the fight to prevent the spread of COVID-19, by ensuring continuity of the clinical testing that they perform in various healthcare setting around the world, so that we can overcome this difficult situation together. To fulfill this mission, Sysmex remains committed to the stable supply of products and services. In addition, to successfully combat the COVID-19 pandemic and bring things back under control as soon as possible, we obtained regulatory approval for PCR test kit (RT-PCR method) and antigen test kit, enhanced PCR testing system through its involvement in an industry-government collaboration with Kobe City, the first example of such collaboration in Japan. The company is also fully engaged in developing new diagnostic technology including measurement of antibody and cytokine.

<https://www.sysmex.co.jp/en/COVID19.html>

### **About Oxford Immunotec**

Oxford Immunotec Global PLC develops, manufactures and sells in-vitro diagnostic drugs for various diseases based on the innovative T cell measurement technology "T-SPOT" developed at Oxford University. Our leading product, the T-SPOT®.TB test, is used for diagnosing infection with active Tuberculosis and latent Tuberculosis. The T-SPOT.TB test has been approved for sale in over 50 countries, including the United States, where it has received pre-market approval from the Food and Drug Administration, Europe, where it has obtained a CE mark. The Company is headquartered near Oxford, U.K. and in Marlborough, MA, the U.S. Additional information can be found at [www.oxfordimmunotec.com](http://www.oxfordimmunotec.com).

## Overview of T-SPOT® *Discovery* SARS-CoV-2

Product name: T-SPOT® *Discovery* SARS-CoV-2

Note: This product is a reagent that can be used for research purposes only and cannot be used for diagnosis.

Riken Genesis Co., Ltd., a subsidiary of Sysmex, is the exclusive distributor of the product in Japan.

## Notes

- 1 News release dated October 22, 2020: “UK Vaccines Taskforce has Selected Oxford Immunotec as the Sole Supplier of T cell Testing for SARS-CoV-2 Specific Responses in New COVID Vaccine Trials”

<https://investor.oxfordimmunotec.com/news-releases/news-release-details/uk-vaccines-taskforce-has-selected-oxford-immunotec-sole>

- 2 News release dated December 2, 2020: “Oxford Immunotec Signs Exclusive Distributor Agreement with RIKEN Genesis, a Subsidiary of Sysmex, to Market the T-SPOT® *Discovery* SARS-CoV-2 Kit for the Measurement of the T cell Immune Response to SARS-CoV-2 Infection in Japan”

<https://investor.oxfordimmunotec.com/news-releases/news-release-details/oxford-immunotec-signs-exclusive-distributor-agreement-riken>