

Shionogi Announces Novel Coronavirus Antigen test agent “LumiraDx SARS-CoV-2 Ag Test Strip” and diagnostic instrument launched in Japan

OSAKA, Japan, May, 24, 2021 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President and CEO: Isao Teshirogi, Ph.D. ; hereafter “Shionogi”) is pleased to announce that Shionogi has launched novel coronavirus (SARS-CoV-2) antigen test “LumiraDx SARS-CoV-2 Ag Test” and “LumiraDx Instrument” in Japan.

The LumiraDx SARS-CoV-2 Ag Test combines high-sensitivity results comparable to those from the PCR with speed and efficiency (results in less than 12 minutes) using samples from a nasopharyngeal swab or nasal swab.¹

The test and platform have already been marketed in Japan, the United States, Europe, and other countries by LumiraDx group. Beginning today in Japan, they will now be marketed by Shionogi and LumiraDx Japan Co., Ltd. (Head Office: Tokyo, Japan; President and CEO: Keisuke Kato).²

Shionogi is committed to “Protecting people worldwide from the threat of infectious diseases” as our key focus. We are not limiting ourselves to the research and development of therapeutic medications, but are also focused on the total care of infectious disease through pre-symptomatic, awareness building, prevention and diagnosis and suppression of exacerbation. To contribute the restoration of social security and safety through the early end of the pandemic, Shionogi will provide this test agent and instrument to medical institute.

About LumiraDx Japan Co., Ltd.

LumiraDx Japan Co., Ltd. is the Japanese company of LumiraDx group, which is headquartered in the United Kingdom. Founded in 2014, LumiraDx develops, manufactures and commercializes an innovative point of care diagnostic platform designed to deliver lab comparable diagnostic results at the point of care in minutes. The company currently has a pipeline of 30 assays across common conditions including infectious disease, cardiovascular disease, diabetes, and coagulation disorders which will all help healthcare decisions affordable and accessible.

Please see the company website for details. [LumiraDx Japan Co., Ltd. website](#)

About LumiraDx SARS-CoV-2 Ag Test Strip

“LumiraDx SARS-CoV-2 Ag Test Strip” is a rapid microfluidic immunofluorescence assay that detects SARS-CoV-2 antigen in nasal swab specimens or nasopharyngeal swab specimens collected from individuals suspected of COVID-19 infection, with results in 12 minutes. In comparison with the PCR using samples from a nasopharyngeal swab, this antigen test agent has a positive agreement rate of 97.5% (39/40) and a negative agreement rate of 97.7% (210/215). In comparison with the PCR using samples from a nasal swab, the test has a positive agreement rate of 97.6% (81/83) and a negative agreement rate of 96.6% (168/174), showing high positive/negative agreement rates with the PCR¹.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market

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conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcomes of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website: <https://www.shionogi.com/global/en/contact.html>

References

1. LumiraDx SARS-CoV-2 Ag Test package insert
<https://www.lumiradx.com/assets/pdfs/covid-19-antigen-test/sars-cov-2-antigen-product-insert/antigen-product-insert-japanese.pdf?v=1>
2. [Press release on April 16, 2021](#)
Shionogi Announces Agreement of Joint Sales with LumiraDx Japan Co., Ltd. for Novel Coronavirus Antigen test agent “LumiraDx SARS-CoV-2 Ag Test Strip” and diagnostic instrument in Japan

Our efforts against COVID-19 are updated on our website as needed. A considerable amount of valuable information on COVID-19 from other websites is also summarized on this page, so please use it for reference: [SHIONOGI website](#)