

FOR IMMEDIATE RELEASE

Company name: H.U. Group Holdings, Inc.
Representative: Shigekazu Takeuchi,
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Securities code: 4544 First Section, Tokyo Stock Exchange

Approval and Launch of Influenza Virus Antigen Reagent for Use with Large Instruments from LUMIPULSE® Series

～ Enables Simultaneous Screening for Novel Coronavirus and Influenza Using a Single Sample ～

Fujirebio Inc. (President & CEO: Takeshi Fujita; Head Office: Shinjuku-ku, Tokyo; hereinafter "Fujirebio"), which is a consolidated subsidiary of H.U. Group Holdings, Inc., has obtained marketing approval from the Ministry of Health, Labour and Welfare for a reagent for use with large-sized instruments from the LUMIPULSE® series of fully automated chemiluminescent enzyme immunoassay (CLEIA) instruments for highly sensitive quantitative measurement of influenza virus antigens and it now plans to launch the approved reagent under the product name "LUMIPULSE Presto Flu-A&B" (hereinafter the "Reagent") from January 15, 2021.

Fujirebio acquired marketing approval for an influenza virus antigen reagent for use with "LUMIPULSE G1200," a mid-sized instrument from the LUMIPULSE series, and "LUMIPULSE G600 II," a small-sized instrument from the series, on November 10, 2020, and this is now being used by medical institutions across Japan under the product name "LUMIPULSE Flu-A&B." The Reagent is a special bottle-type reagent for use with "LUMIPULSE L2400" and "LUMIPULSE Presto II," which are large-sized instruments from the LUMIPULSE series. The Reagent can be used in combination with "LUMIPULSE Presto SARS-CoV-2 Ag," a high-sensitive antigen reagent for novel coronavirus, to enable simultaneous screening for novel coronavirus and influenza virus using a single sample.

The impact of the launch on our consolidated business results for the fiscal year ending March 31, 2021 is expected to be insignificant but we will promptly disclose any events arising in the future which require disclosure.

Product Overview

Generic Name: Influenza Virus Kit



Product Name: LUMIPULSE Presto Flu-A&B

(Marketing Approval No.: 30200EZX00090000)

Target Market: Japan

Marketing Authorization Holder: Fujirebio Inc.

[For Reference: List of Influenza Virus Antigen Reagents]

Product Name	LUMIPULSE Presto Flu-A&B	LUMIPULSE Flu-A&B
Date of Marketing Approval	December 22, 2020	November 10, 2020
Supported Devices	LUMIPULSE L2400 LUMIPULSE Presto II	LUMIPULSE G1200 LUMIPULSE G600 II
Processing Capacity	240 tests per hour	LUMIPULSE G600 II: 60 tests per hour LUMIPULSE G1200: 120 tests per hour
Test Duration	Approx. 25 min.	Approx. 30 min.
Product Image		

[For inquiries about this announcement, please use the contact details below]

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