

News Release

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

Approval of Manufacturing and Marketing Authorization for ESPLINE[®] SARS-CoV-2 & Flu A+B, the Rapid Assay for Simultaneous Detection of SARS CoV-2 and Influenza Viruses

Tokyo, Japan, August 13, 2021 --- H.U. Group Holdings Inc. today announced that its wholly-owned subsidiary, Fujirebio Inc. (President & CEO: Takeshi Fujita; Head Office: Shinjuku-ku, Tokyo; hereinafter "Fujirebio"), obtained on August 13, 2021, an approval to manufacture and market ESPLINE[®] SARS-CoV-2 & Flu A+B ("the Kit"), the rapid assay for simultaneously detecting SARS-CoV-2 antigens and influenza virus antigens. Fujirebio will launch the product as soon as it is ready to market it.

The Kit constitutes the in vitro diagnostic agent using Fujirebio's rapid diagnosis platform based on the immunochromatographic technology that employs an enzyme immunoassay for measurement. The Kit uses nasopharyngeal or nasal cavity swabs as samples without requiring any special devices. It concurrently detects both SARS-CoV-2 and influenza viruses in a sample within 20 minutes through simple operations.

Symptoms of COVID-19 and influenza are very similar, especially fever, fatigue and respiratory symptoms such as cough. It is therefore necessary to identify viral species and discriminate between two diseases at early stages. The Kit enables the concurrent detection of both SARS-CoV-2 antigens and influenza virus antigens in the same sample. It is expected to help reduce the patient burden during sample collection, lessen the infection risk for healthcare professionals, and speed up identification of two infectious diseases. Asahikawa Facility and Ube Facility of Fujirebio will manufacture the Kit, having a production capacity of 480,000 test kits per week at maximum.

Fujirebio will continue to develop reagents for COVID-19 and contribute to infection control.

Product Overview

Generic name: SARS-CoV-2 virus antigen kit

Influenza virus kit

Product name: ESPLINE® SARS-CoV-2 & Flu A+B

(Manufacturing and marketing authorization number: 30300EZX00068000)

Target Market: Japan

Marketing Authorization Holder: Fujirebio Inc.

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