



To Whom It May Concern,

Company name: Miraca Holdings, Inc

Name of President and Group CEO Representative: Shigekazu Takeuchi

Securities code: 4544 - 1st section of the Tokyo

Stock Exchange

Authorization to manufacture and market a rapid diagnostic test kit for the Novel Coronavirus (SARS-CoV-2) antigen

TOKYO, May 13, 2020 – Fujirebio Inc, (hereafter "Fujirebio", headquartered in Shinjuku, Tokyo, President and CEO, Goki Ishikawa), our consolidated subsidiary, announces that it has received the manufacture and market authorization for ESPLINE® SARS-CoV-2 (hereafter, "the test kit"), a quick and simple test kit to detect the Novel Coronavirus (SARS-CoV-2) antigen, and will start marketing.

The test kit is built up on Fujirebio's rapid test platform, which uses immuno-chromatography technology based on the principle of enzyme immunoassay, to detect the SARS-CoV-2 antigen from pharyngeal swab fluid sample.

As a feature, the test kit utilizes several kinds of antibodies that were originally established by Fujirebio to capture protein inside SARS-CoV-2 and coloring method based on enzyme reaction to detect the antigen-antibody complex. The test kit shows test result within 30 minutes after the reaction begins (positive results: 10 - 30 minutes, negative results: 30 minutes). Fujirebio will manufacture the test kit in Ube Factory (Ube City, Yamaguchi Prefecture) and its manufacturing capacity is 200,000 tests/week.

The impact which the test kit will make on the consolidated performance in the fiscal year ending March 2021 is currently under review.

We, as Miraca Group, are committed to establish a solid framework for clinical testing for the Novel Coronavirus disease through PCR tests conducted by our subsidiaries, SRL, Inc and Japan Clinical Laboratories, Inc, and by providing the test kit developed by Fujirebio.

<Product summary>

Generic name SARS Coronavirus test kit Product name ESPLINE® SARS-CoV-2

(Authorization number for In-vitro Diagnostics 30200EZX0002600)

Packing unit 100 tests/kit

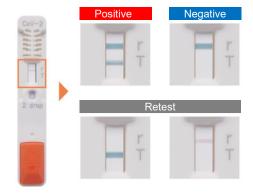
Available market Japan

Manufacturer Fujirebio, Inc

<Photos of product>







About Fujirebio

Fujirebio is a global leader in the field of high-quality in vitro diagnostics (IVD) testing. It has more than 50 years' accumulated experience in the conception, development, production and worldwide commercialization of robust IVD products.

Founded in 1950 in Tokyo, Japan, Fujirebio has over the years concluded a number of successful acquisitions of best-in-class IVD companies. Examples include Centocor Diagnostics in 1998, CanAg Diagnostics in 2006 and Innogenetics in 2010. Today, Fujirebio's global presence includes offices in the United States, Latin America, Europe and Asia as well as a vast international distribution network.

Fujirebio has a strong and long-lasting tradition of collaborating with experts in the worldwide clinical community in the development of high-quality routine and truly novel biomarkers that cover a variety of

disease states. Its IVD product lines span the range from specialized manual and automated testing to fully automated routine clinical laboratory testing solutions.

Fujirebio is a wholly-owned subsidiary of Miraca Holdings Inc. (Miraca Holdings Inc. listed on the Tokyo Stock Exchange – TYO: 4544) and employs more than 1,200 people in Asia, Europe and America.

For inquiries

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