

January 29, 2021 Denka Company Limited

Application for PMDA Approval of a Test Kit for Simultaneously Detecting Both the COVID-19 Coronavirus and Influenza Viruses in Japan

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter, "Denka") has developed a rapid antigen test kit that enables the simultaneous detection of both SARS-CoV-2 (the COVID-19 coronavirus) and influenza viruses using one device (hereinafter the "Combo Kit"), and today submitted an application for approval as an in-vitro diagnostic in Japan to the Pharmaceuticals and Medical Devices Agency (PMDA).

The Combo Kit uses the immunochromatography method to detect SARS-CoV-2 antigens and influenza (Type-A and Type-B) antigens using one device, and quickly determines results, positive or negative. It is difficult to diagnose SARS-CoV-2 and influenza infections from symptoms. The use of the Combo Kit, which is able to detect both at the same time, is expected to enable patients to receive the proper treatment and reduce the burdens borne by health care workers.

Denka has been involved in the test reagent business for years, where it has provided QuickNaviTM-Flu2, an influenza rapid antigen test kit, and QuickNaviTM-Adeno2, an adenovirus rapid antigen test kit. Additionally, last year on August 13, Denka released QuickNaviTM-COVID19 Ag, the SARS-CoV-2 rapid antigen test. Working together with its sales partner, Otsuka Pharmaceutical Co., Ltd., Denka supplies this test kit to medical institutions nationwide. QuickNaviTM-COVID19 Ag is a reagent that detects the existence of SARS-CoV-2 antigens in a nasopharyngeal swab specimen or a nasal swab specimen without requiring a specific test device, in about 15 minutes. Because it enables any hospital to quickly and simply test for the disease, it is increasingly used. After its release, to contribute to the expansion of antigen testing, Denka increased its production capacity equivalent from 100,000 tests a day in October to up to 130,000 tests a day in November.

Denka recognizes it bears the social responsibility of carrying out measures to prevent infection. Through a sufficient supply capacity, Denka will help improve COVID-19 antigen testing in clinics and hospitals.

About Denka

Denka is a chemical manufacturer headquartered in Chuo-ku, Tokyo. The company specializes in developing business activities on a global scale across a wide range of fields, from inorganic and organic chemicals, to electronic materials and pharmaceuticals. Founded in 1915, Denka has steadily continued to develop and manufacture products that contribute to the development of society by fully utilizing its unique concepts and technological capabilities. Upholding its corporate slogan, "Possibility of chemistry" the company and its president, Manabu Yamamoto, are committed to contributing to the sound development of the society while sincerely tackling the challenges that the society is now confronting.

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