

## Denka Files Application for Japanese in Vitro Diagnostics Approval of a Simple and Rapid Testing Kit Infection for the COVID-19 Novel Coronavirus

Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter, “Denka”) submitted an application to the Pharmaceuticals and Medical Devices Agency (PMDA) on July 20, 2020, for domestic regulatory approval of a simple and rapid testing kit (hereinafter, the “testing kit”) to detect the COVID-19 novel coronavirus, as an in vitro diagnostic agent.

Denka collaborated with the National Institute of Infectious Diseases (NIID) on the research and development of the diagnostic method. The development activities have gained the cooperation and support of the authorities concerned, public agencies and research institutions in Japan and overseas. For example, Denka receives antibodies and antigens from NIID through the involvement of a research team from the Japan Agency for Medical Research and Development (AMED).

The testing kit uses an immunochromatographic method to detect antigens of the COVID-19 novel coronavirus (SARS-CoV-2). Without requiring a compatible analyzer, the testing kit can quickly discern between positive and negative results. Denka will develop the capacity for the mass production of up to 100,000 tests per day, in preparation for prompt deliveries to medical institutions after domestic regulatory approval is obtained.

Denka considers measures against the COVID-19 novel coronavirus to be the company’s social responsibility and will strive to meet the needs of healthcare providers and contribute to the expansion of testing systems in cooperation with other concerned specialists and organizations.

### References:

- Notice Regarding the Status of Development of Simple and Rapid Testing Kits for the COVID-19 Novel Coronavirus Infection, March 24, 2020  
[https://www.denka.co.jp/eng/storage/news/pdf/275/20200324\\_denka\\_seiken\\_covid19\\_en.pdf](https://www.denka.co.jp/eng/storage/news/pdf/275/20200324_denka_seiken_covid19_en.pdf)
- Notice Regarding Start of the Development of Simple and Rapid Testing Kits for COVID-19, Novel Coronavirus Infection, February 13, 2020  
[https://www.denka.co.jp/eng/storage/news/pdf/267/20200213\\_denka\\_seiken\\_covid19\\_en.pdf](https://www.denka.co.jp/eng/storage/news/pdf/267/20200213_denka_seiken_covid19_en.pdf)

**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 society while sincerely tackling the challenges that society is now confronting.

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