

Approval for Manufacturing and Marketing of COVID-19 Rapid Antigen Test in Japan  
~ QuickNavi™- COVID19 Ag to be distributed to Japanese Medical Institutions starting on August 13 ~



< Rapid Antigen Test for COVID-19, QuickNavi™- COVID19 Ag >

On August 11<sup>th</sup>, Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter, “Denka”) received approval for the manufacturing and marketing of rapid antigen test for COVID-19 in Japan. As the in vitro diagnostic test, QuickNavi™- COVID19 Ag is to be available for sales for medical institutions from August 13<sup>th</sup> with the capacity to produce up to 100,000 tests per day at Denka’s Gosen Site (Gosen-shi, Niigata). Denka’s marketing alliance partner, Otsuka Pharmaceutical Co., Ltd. (headquarters: Chiyoda-ku, Tokyo; President and Representative Director: Makoto Inoue) also launch QuickNavi™- COVID19 Ag on September 1st. The impact of this development on the consolidated financial statements for the coming fiscal year ending March 2021 is under evaluation. In case this event would give a substantial impact, Denka would announce accordingly.

QuickNavi™- COVID19 Ag detects the antigens from SARS-CoV-2 in a nasopharyngeal swab sample within 15 minutes without the need for special testing equipment allowing rapid, simple and near patient testing at healthcare institutions. In addition, to prepare for seasonal influenza season in Japan, Denka is now developing the test to detect both SARS-CoV-2 and influenza antigens from the single swab sample. Furthermore, Denka is proactively working to shorten the time to results and to add other types of specimen to be used.

Considering measures against the COVID-19 novel coronavirus to be the company’s social responsibility, Denka began developing this product this February, leveraging the technologies and know-how that the company has built over the years through the development and manufacturing of diagnostic reagents for infectious diseases. In response to the rapid global spread of COVID-19 and the increasing demand for the quick expansion of testing systems in Japan, Denka has collaborated with the National Institute of Infectious Diseases (NIID) through the involvement of the Japan Agency for Medical Research and Development (AMED) project to develop the test. Thanks to their support, Denka accelerated the process by receiving

antibodies and antigens from NIID. While it normally takes at least eighteen months to two years from product design to receive approval for manufacturing, Denka only took six months to receive the approval with support from the relevant authorities, public agencies, and research institutions in Japan and overseas.

Denka believes that this product will be a useful tool in COVID-19 testing system and will eventually contribute to improve people's quality of life.

< QuickNavi™- COVID19 Ag Assay Procedure and Interpretation of the Result \*Japanese >

<Product Outline>

General Name	SARS Coronavirus Antigen Kit
Product Name	QuickNavi™- COVID19 Ag
Approval No.	30200EZX00047000
Specimen	Nasopharyngeal swab
Reading Time	15 minutes after addition of specimen
Storage	Room temperature (2 to 30°C)
Shelf life	12 months from the date of manufacturing
Units/Pack	10 Tests/pack
Targeted Market	Japan Only
Unit Price	60,000 yen for 10 tests
Manufacturer/Distributor	Denka Company Limited

<Product Photo>



Positive



Negative



References:

- Denka Files Application for Japanese in Vitro Diagnostics Approval of a Simple and Rapid Testing Kit Infection for the COVID-19 Novel Coronavirus  
[https://www.denka.co.jp/eng/storage/news/pdf/290/20200720\\_denka\\_covid19\\_testingkit\\_en.pdf](https://www.denka.co.jp/eng/storage/news/pdf/290/20200720_denka_covid19_testingkit_en.pdf)
- 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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