

## Expansion of Intended Use and Specimen Types for Denka's COVID 19 Ag Rapid Test kit ~To diminish healthcare and patient burden in SARS-CoV-2 and Influenza antigen testing~

On October 2<sup>nd</sup>, Denka Company Limited (headquarters: Chuo-ku, Tokyo; president: Manabu Yamamoto; hereinafter, “Denka”) has received approval from the Ministry of Health, Labour and Welfare, to partially change the market authorization of QuickNavi<sup>TM</sup>-COVID19 Ag, to add a new specimen type.

Under the new authorization, a nasal swab specimen (a specimen collected by inserting a swab from nasal cavity by about 2 centimeters), in addition to the conventional nasopharyngeal swab specimen (a specimen collected from deep in the nasal cavity), can be used with QuickNavi<sup>TM</sup>-COVID19 Ag. Furthermore, patients are now allowed to collect specimen themselves under the guidance of a healthcare professional. This reduces the risk of transmission to healthcare professionals and the burden on patients.

In addition, to be prepared to the coming Flu season, specimens of QuickNavi<sup>TM</sup>-COVID19 Ag taken from a single swab can also be used with QuickNavi<sup>TM</sup>-Flu2 influenza<sup>1</sup> rapid antigen test or QuickNavi<sup>TM</sup>-RSV2 RS<sup>2</sup> rapid antigen test.

To expand rapid antigen testing, Denka will put efforts on tests that are easy to use. Those include higher sensitivity and shorter reading time of QuickNavi<sup>TM</sup>- COVID19 Ag in addition to the test that can detect both influenza and SARS-CoV-2 viruses at the same time.

Recommendations (\*3) issued by the Japanese Association for Infectious Diseases focus on the need for early diagnosis and early treatment as well as influenza vaccination concerning SARS-CoV-2 and influenza will simultaneously spread. As the sole domestic manufacturer to supply influenza vaccines as well as rapid antigen detection test for various viruses (QuickNavi<sup>TM</sup> series), Denka is working to prevent the spread of infection through the prevention to diagnostics.

Denka considers the fight against infectious diseases to be its social responsibility and, with the cooperation and support of relevant authorities, public agencies and research institutions in Japan and overseas, is conducting research and development from various perspectives to meet the needs of healthcare professionals and contribute people's quality of life by help improve prevention and diagnostic systems.

1. Quick Procedure Guide and Examples of the Results \*Japanese

**操作方法**

クイックナビ™-COVID19 Ag クイックナビ™ COVID19 Ag ・ クイックナビ™-Flu 2 クイックナビ™ Flu 2  
クイックナビ™-RSV2 クイックナビ™ RSV2

Flu2-RSV2  
~5分  
COVID19 Ag  
~15分

検査結果の判定へ

検査結果の判定：判定例

○ ×

コントロールラインに発色が認められる  
C T 陽性 C T 陰性

コントロールラインに発色が認められない  
C T 無効例

上記は判定例を模式的に表したものであり、実際の見え方とは異なります。

2. Impact on consolidated financial results for FY2020

Denka will promptly make an announcement if this development is expected to have a considerable impact on Denka's consolidated financial results for FY2020.

(\*1) Influenza virus

Most common symptoms include a fever of over 38° C, headache, arthralgia and myalgia, and fatigue, and these symptoms usually develop rather rapidly. As in the case of the common cold, sore throat, runny nose and coughing occur as well. Children, rarely, may develop acute encephalopathy, and the elderly and those with weak immunity may develop secondary pneumonia or other severe symptoms.

(Source: MHLW website "Q&A on Influenza Q&A FY2019)

<https://www.mhlw.go.jp/bunya/kenkou/kekaku-kansenshou01/qa.html>

(\*2) RS virus

Respiratory syncytial virus (RSV) is the most frequent cases for respiratory infections in infants and children. It typically occurs in the winter but recent outbreaks in Japan have tended to start during summer and autumn. A majority of children experience their first RSV infection by one year of age, with almost all experiencing their first RSV infection by two years of age. RSV infections in infants and children need to be monitored carefully as lower respiratory tract infections (bronchitis, pneumonia, etc.) can cause serious respiratory complications.

(Source: Manual of Pediatric Infectious Diseases edited by Japanese Society for Pediatric Infectious Diseases)

(\*3) Recommendations of Japanese Association for Infectious Diseases "Preparing for Influenza and COVID-19 for coming winter" (Japanese only)

[http://www.kansensho.or.jp/uploads/files/guidelines/2008\\_teigen\\_influenza\\_covid19.pdf](http://www.kansensho.or.jp/uploads/files/guidelines/2008_teigen_influenza_covid19.pdf)

References:

- 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 ~  
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- Denka Files Application for Japanese in Vitro Diagnostics Approval of a Simple and Rapid Testing Kit Infection for the COVID-19 Novel Coronavirus, July 20, 2020  
[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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