November 8, 2021
Denka Company Limited

Notice of Voluntary Recall of Certain Lots of the COVID-19 Rapid Antigen Test Kit

Denka Company Limited (headquarters: Chuo-ku, Japan; president: Toshio Imai; hereinafter, "Denka") is voluntarily recalling (Class II*) certain lots of the rapid antigen test kit for SARS-CoV-2 QuickNavi™ -COVID19 Ag, since it was found that there was an increased frequency of false positives in certain lots for which defective parts were used.

We sincerely apologize for the concern and inconvenience this recall may cause to you and your facility. Denka will take all possible measures to prevent a recurrence of this problem by further strengthening its quality control.

The impact of this matter on Denka's consolidated business results for fiscal year 2021 is still under scrutiny.

* Class II means that use of the product is likely to cause temporary or medically reversible adverse health consequences, or is unlikely to cause serious adverse health consequences.

1. Summary of the recall

It was found in certain lots of QuickNavi™ -COVID19 Ag (SARS-CoV-2 antigen test kit), manufactured and sold by Denka, that the false positive rate may increase some time after manufacturing due to the use of certain defective components.
Therefore, Denka is voluntarily recalling the following lots. With the safety of users as its top priority, Denka has provided information to the facilities to which it delivered the products and asked them to take appropriate measures.

2. Overview of *in-vitro* diagnostic products to be recalled

① Product name
Quick Navi™ -COVID19 Ag
(Manufacturing approval number: 30200EZX00047000, August 11, 2020)

(2) Intended use
Detection of SARS-CoV-2 antigens in nasal and nasopharyngeal swab specimens
(Aid in the diagnosis of SARS-CoV-2 infection)

3. Product lots subject to recall

Of the product lots with an expiration date of December 2021, those with lot numbers 0750121 to 0850121 are subject to recall.

(1) Quick Navi™ -COVID19 Ag (Item number: 326119)

Lot number	Number of boxes shipped	Time of shipment
0760121	11,000	December 14, 2020
0790121	13,000	December 18, 2020
0800121	13,000	December 21, 2020
0820121	13,000	December 23, 2020
0830121	13,000	December 24, 2020
0840121	7,000	December 25, 2020
0850121	8,000	December 25, 2020

(2) Quick Navi™ -COVID19 Ag (Otsuka Pharmaceutical Co., Ltd.) (Item number: 326140)

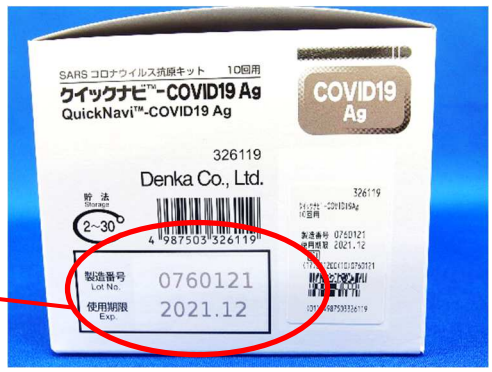
Lot number	Number of boxes shipped	Time of shipment
0750121	13,000	December 15, 2020
0770121	13,000	December 16, 2020
0780121	13,000	December 17, 2020
0810121	13,000	December 22, 2020

* Each box contains 10 tests.

* This voluntary recall covers the product which determine the presence or absence of SARS-CoV-2 antigens in approximately 15 minutes. The test kits currently sold by Denka and Otsuka Pharmaceutical, which take 8 minutes to obtain a result, are not subject to recall.

(3) Location of lot number and expiration date (The lot number and expiration date are indicated on the outer packaging.)

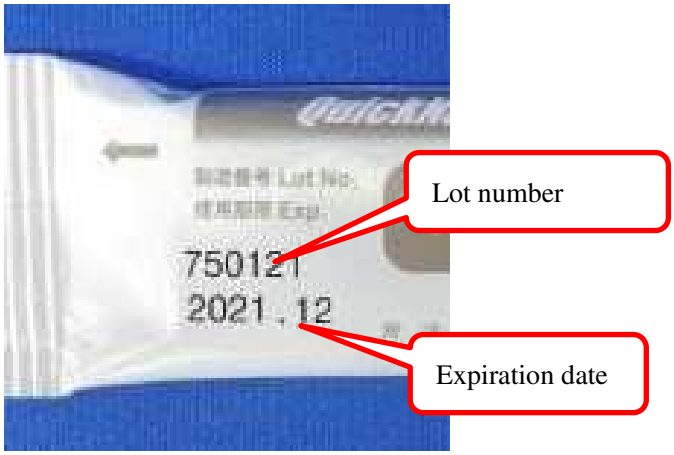
[Product sold by Denka] Photo of outer packaging　　Indicated on the side of the outer packaging.



[Product sold by Otsuka Pharmaceutical]

Photo of outer packaging　　Indicated on the side of the outer packaging.

Photo of test devices



4. Reason for recall and its causality

It was found that the false positive rate may increase over time after manufacturing in lots subject to recall due to certain defective components used. Therefore, Denka has decided to initiate a voluntary recall of the product and has begun providing information to the facilities to which it delivered the product.

5. Serious adverse events

An impact on safety and efficacy cannot be ruled out when the product subject to recall is used, since the false positive rate may increase as mentioned above.
However, Denka does not believe that any serious adverse events will occur, as a diagnosis is made comprehensively taking into account to other test results and clinical symptoms. To date, there have been no reports of adverse events affecting the patient associated with this problem.

6. How to recall the product

Denka will contact the relevant facilities as soon as the method of the product recall has been decided.

[For Inquiries about This Press Release from Media]
Corporate Communications Dept. Tel: +81-3-5290-5511
[For Inquiries about This Press Release from Medical Personnel]
Domestic Reagents Dept. of Vaccines and Diagnostics Business Headquarters, Life Innovation
Tel: +81-3-6214-3235