November 15, 2021
Denka Company Limited

# Notice of Voluntary Recall of Certain Lots of the COVID-19 Rapid Antigen Test Kit (Second Notification)

Following the notification on November 8th, Denka Company Limited (headquarters: Chuo-ku, Japan; president: Toshio Imai; hereinafter, "Denka") announces it has decided to initiate a Class II* voluntarily recall of additional product lots for QuickNavi™ -COVID19 Ag rapid antigen test kit for the safety of users as its top priority.

"We sincerely apologize for any concerns or inconveniences that the decision of this voluntarily recall following on November 8th may cause users of the product. I deeply regret that this situation has occurred and I, as a president, am committed to taking the lead in the implementation of all possible measures to prevent a recurrence of this problem". (Toshio Imai, Representative Director, President, Denka Company Limited)

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 and reasons for the recall

Following our previous decision on November 8th this year to recall certain lots of the 15-minute antigen test kit due to the use of certain defective components, we started to conduct additional accelerated studies using newer lots that can determine the results within 8 minutes. Some of the 8-minute antigen test kits showed signs of an increased rate of false positives.
Therefore, Denka is voluntarily recalling additional product lots with the following serial numbers. Placing the safety of users to our 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 in Japan: 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

The products with serial numbers 0861061 to 0921071 and 0981071 to 1031071 are subject to this recall.

Total: 91,700 kit boxes (917,000 tests)

(1) QuickNavi™ -COVID19 Ag- (Item number: 326119)

| Lot number | Number of boxes shipped | Time of shipment |
|---|---|---|
| 0891071 | 8,000 boxes (80,000 test kits) | July 8, 2021 |
| 0921071 | 7,550 boxes (75,500 test kits) | July 14, 2021 |
| 0981071 | 8,000 boxes (80,000 test kits) | July 27, 2021 |
| 0991071 | 8,000 boxes (80,000 test kits) | July 28, 2021 |
| 1011071 | 6,314 boxes (63,140 test kits) | July 29, 2021 |
| 1021071 | 4,000 boxes (40,000 test kits) | August 2, 2021 |

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

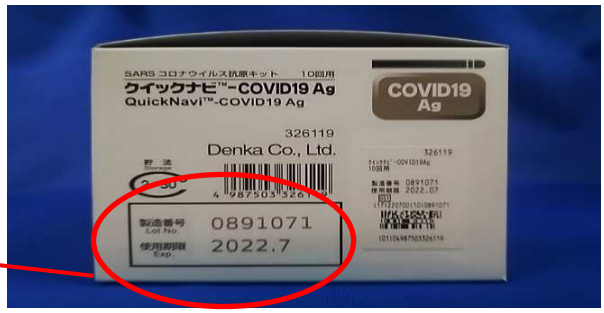
| Lot number | Number of boxes shipped | Time of shipment |
|---|---|---|
| 0861061 | 6,800 boxes (68,000 test kits) | July 5, 2021 |
| 0871061 | 6,800 boxes (68,000 test kits) | July 6, 2021 |
| 0881071 | 6,800 boxes (68,000 test kits) | July 7, 2021 |
| 0901071 | 8,000 boxes (80,000 test kits) | July 9, 2021 |
| 0911071 | 8,000 boxes (80,000 test kits) | July 12, 2021 |
| 0981071 | 1,436 boxes (14,360 test kits) | July 27, 2021 |
| 1021071 | 4,000 boxes (40,000 test kits) | August 2, 2021 |
| 1031071 | 8,000 boxes (80,000 test kits) | August 3, 2021 |

Note: This voluntary recall covers specific lots of the test kit which determines the presence/absence of SARS-CoV-2 antigens within 8 minutes.

(3) Location of serial numbers and expiration date (The serial 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.

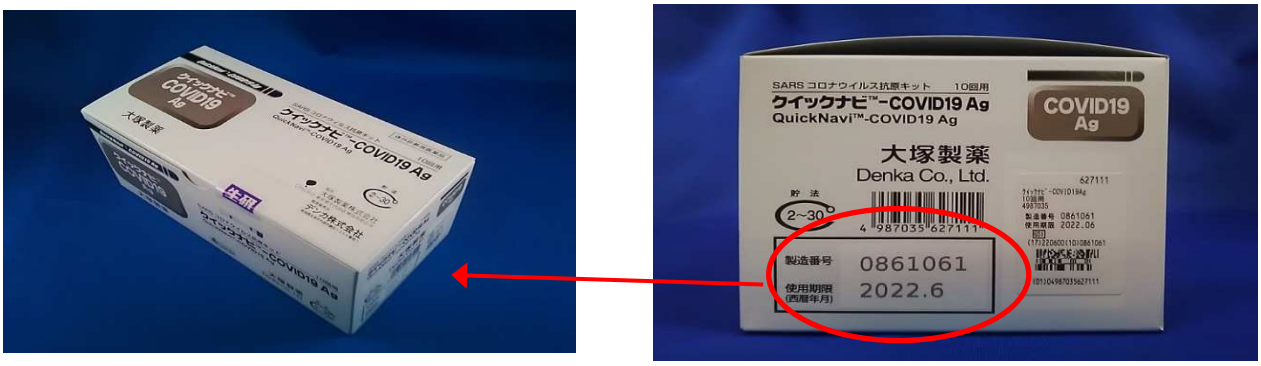



Photo of test devices


4. 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 health consequences 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.

5. How to recall the product

Denka will contact the relevant facilities as soon as the method the product recall has been decided. For the facilities that purchased the product through a pharmaceutical wholesaler, we will notify the recall and at the same time, will recall the product immediately.

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