

September 2, 2021

To all who have received the vaccination at school

Important: Second Report regarding contamination by a foreign substance in a vaccine manufactured by Moderna

Nakanishi Gakuen Educational Foundation  
Director of General Affairs

We would like to apologize for the inconvenience and concern caused by the contamination of some of the vaccines manufactured by Moderna that were administered at our school. We would like to inform you of the following report dated September 1, 2021.

Common name: Coronavirus-modified uridine RNA vaccine (SARS-CoV-2)

Trade Name: COVID-19 Vaccine Moderna Intramuscular Injection

Lot 3004667 (approx. 57,000 vials) (approx. 570,000 doses), the lot applying to our university

Lot 3004734 (approx. 52,000 vials) (approx. 520,000 doses)

Lot 3004956 (approx. 54,000 vials) (approx. 540,000 doses)

#### Summary of investigation results

The foreign substance in question was a fragment of manufacturing equipment (stainless steel). Stainless steel is used in medical devices such as artificial heart valves and metal staples. Even in the event of extremely small fragments of the metal having been injected into the muscle, it is unlikely to increase health risk.

In addition to the above summary of the results of the survey, both the vials (vaccine bottles) and syringes (injection tubes) were visually inspected for contamination with foreign substances, colors changes, and other abnormalities during dispensing, and no problems were found prior to vaccination.

In addition, there have been no reports of health problems believed to have occurred in relation to this case.

The Ministry of Health, Labour and Welfare and Takeda Pharmaceutical Company

Limited have also informed us that they have not received any reports of any safety concerns that may have arisen in relation to this case.

We will continue to work closely with the Ministry of Health, Labour and Welfare and Takeda Pharmaceutical Company Limited to ensure prompt disclosure of information and prompt response in case there are any matters that require our attention.

<Ministry of Health, Labour and Welfare website>

[https://www.mhlw.go.jp/stf/newpage\\_20855.html](https://www.mhlw.go.jp/stf/newpage_20855.html)

<Takeda Pharmaceutical Company Limited>

<https://www.takeda.com/ja-jp/announcements/investigation-of-suspended-lots-of-covid-19-vaccine-in-japan/>