'Place them in the trash': FDA warns against using Innova's rapid COVID-19 antigen tests

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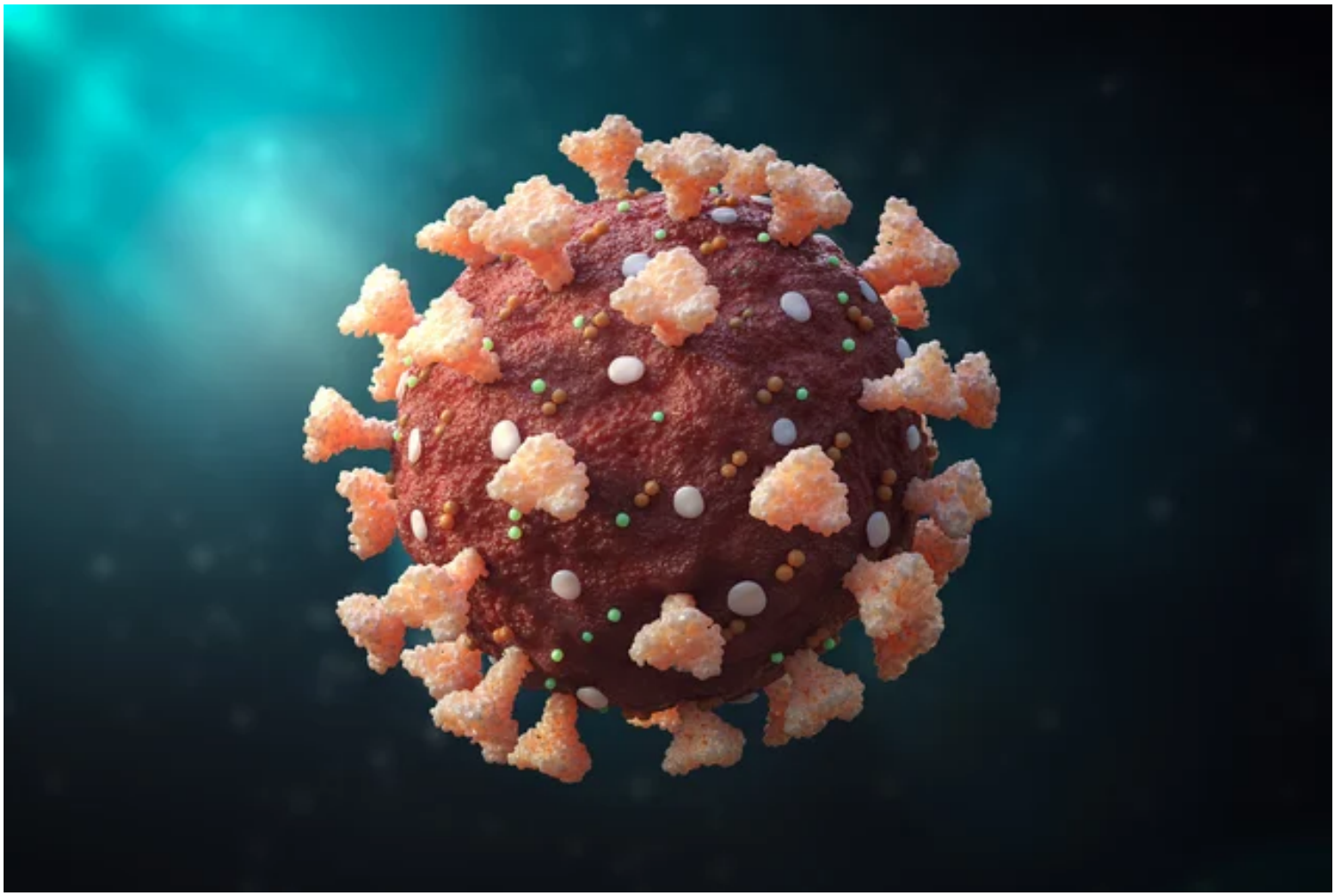

The U.K. government previously purchased more than 380 million rapid tests from Innova, to help set up programs capable of screening millions of people per day. (libre de droit/iStock/Getty Images Plus)

The FDA issued a stark warning to the public urging them to stop using rapid COVID-19 antigen tests developed by Innova Medical Group, the company previously tapped by the U.K. government for hundreds of millions of kits to help regularly screen the country's population.

The move follows a Class I recall, the FDA's most serious, launched by Innova in late April amid "significant concerns" about the test's accuracy—and alongside an official warning letter delivered to the company this week.

The agency's first recommendation was straightforward: "Stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test. Destroy the tests by placing them in the trash or return the tests to Innova using the FedEx return label that was included with the recall letter that Innova sent to customers."

Though Innova previously applied for a regulatory green light, the test has not been authorized or approved by the FDA for use in the U.S.—however, during inspections of the company's California facilities in March and April, FDA investigators said they found the test was already being sold and distributed.

The FDA also said that the labeling of the diagnostic, which comes in different versions, included performance claims that did not match up with results seen in clinical studies—and that the data Innova submitted for review "was identical to data previously provided by other manufacturers" in separate requests for emergency COVID authorizations, raising additional questions.

Innova's kit includes a nasal swab and a lateral flow test strip, which in less than a half-hour produces colored lines to display a positive reading, similar to a pregnancy test. However, the FDA said that false-negative and false-positive results may lead to delayed diagnoses, inappropriate treatment and the further spread of the virus.

In a statement to Fierce Medtech, Innova said it has completed some corrective actions, while others are still underway, and that the U.S. recall was launched to reclaim tests distributed to employees, clinical studies and to customers for early evaluation. The company said it plans to seek an emergency use authorization and comply with all FDA requirements.

It has contracted with the Chinese manufacturer Xiamen Biotime Biotechnology to produce the tests for international distribution. According to Innova, Biotime previously submitted performance data to the agency without seeking an EUA, while the company later presented equivalent data for the same test under the Innova brand.

The U.K. government previously purchased more than 380 million rapid tests from Innova, to help set up programs capable of screening millions of people per day—in the run-up to offering free COVID-19 testing nationwide at least twice per week.

A November 2020 analysis by researchers at the University of Oxford found Innova's tests could be more or less accurate depending on who was using them—ranging from lab scientists to trained healthcare professionals to the general public—but determined the tests overall had a low failure rate and high specificity, despite some variations seen in production batches. Still, Innova's test and antigen diagnostics more broadly have been seen as less accurate compared to gold-standard, lab-based PCR screening.

In its message to the public, the FDA said that a person should consider being retested if they used Innova's diagnostic within the past two weeks.

Editor's note: This story has been updated with comment from Innova.