Innova Medical Group Recalls Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- **Innova SARS-CoV-2 Antigen Rapid Qualitative Test** (also distributed under the names Innova COVID-19 Self-Test Kit (3T Configuration), Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration))
- **Lot codes:**
  - **25T (25 tests per box) -** U2101750, U2101751, X2006004, X2008001, X2008010, X2009002, X2009004, X2009013, X2009016, X2010004, X2010010, X2011005, X2011006, X2011007, X2011008, X2011009, X2011012, X2011013, X2011015, X2011016, X2011017, X2011025, X2011051, X2011052, X2012001, X2012002, X2012004, X2012005, X2012008, X2101002, X2101004, X2101014, X2101031, X2101038
  - **3T (3 tests per box) -** U2102003, X2012310
  - **7T (7 tests per box) -** U2101748, U2102001, U2102002, X2012711, X2103792
- **Manufacturing Dates:** September 1, 2020 to March 3, 2021
- **Distribution Dates:** November 2, 2020 to March 22, 2021
- **Devices Recalled in the U.S.:** At least 77,339
- **Date Initiated by Firm:** March 24, 2021

Device Description

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person has an active COVID-19 infection. The test used a nasal swab sample and test strip to detect specific proteins, called antigens, from the SARS-CoV-2 virus. If the nasal sample had SARS-CoV-2 antigens, a colored test line should have appeared on the test strip, indicating that the person may have COVID-19. If the nasal sample did not have SARS-CoV-2 antigens, a colored line should not have appeared on the test strip. The test has not been authorized, cleared, or approved by FDA for commercial distribution in the United States.

Reason for Recall

Innova Medical Group is recalling its SARS-CoV-2 Antigen Rapid Qualitative Test. Labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. The performance characteristics of the test have not been adequately established, presenting a risk of false results.

- **False-negative results** may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2, which may cause patient harm including serious illness and death. False-negative results can also lead to further spread of the SARS-CoV-2 virus, including when presumed negative patients are grouped into cohorts in health care, long-term care, and other facilities based on false test results.
- **False-positive results** could lead to a delay in the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness, which could be another life-threatening disease that is not SARS-CoV-2. False-positive results could also lead to further spread of the SARS-CoV-2 virus when presumed positive patients are grouped into cohorts based on false test results.

Who May Be Affected

- People who were tested using these devices
- Health care providers who may have access to and use these tests or whose patients have used these tests
- Organizers of large testing programs, such as on college campuses, who may be using and distributing these tests for diagnostic use

What to Do

On April 23, 2021, Innova Medical Group sent all affected device users an Urgent Medical Device Recall letter. The letter provided the following information:

- Do not use these tests to screen for or diagnose COVID-19.
- Identify and remove all affected tests from inventory.
- Either destroy the tests by placing them in the trash or return the tests using the FedEx return label that was included with the letter Innova sent to its customers.
- Complete and return the form Innova sent to its customers, indicating the number of destroyed or returned tests.

The FDA also recommends:

- **Test users and caregivers:** Talk to your health care provider if you think you were tested with the Innova SARS-CoV-2 Antigen Rapid Qualitative Test and you have concerns about your test results.

- **Health care providers:** If the test was given less than two weeks ago, consider retesting your patients using a different SARS-CoV-2 diagnostic test if you suspect an inaccurate result. If testing was performed more than two weeks ago and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Testing program organizers:** Notify participants in your testing program to discontinue diagnostic use of these tests and to use an FDA-authorized test to continue testing. For listings of FDA-authorized tests, see:
    - FDA-Authorized Molecular Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - FDA-Authorized Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Report any problems you experience with the Innova SARS-CoV-2 Antigen Rapid Test to the FDA, including suspected false results.

For more information, please see the FDA's June 2021 safety communication, Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test (/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication).

Contact Information

Customers with questions about this recall should contact Linda Weinreb at Linda.Weinreb@innovamedgroup.com (mailto:Linda.Weinreb@innovamedgroup.com) or call 747-494-0852.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) *they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.*