Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is warning the public to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for diagnostic use. The FDA has significant concerns that the performance of the test has not been adequately established, presenting a risk to health. In addition, 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. Finally, the test has not been authorized, cleared, or approved by the FDA for commercial distribution or use in the United States, as required by law.

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test is 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).

On April 23, 2021, Innova Medical Group recalled their Innova SARS-CoV-2 Antigen Rapid Qualitative Test. The FDA has identified this recall as a Class I recall (/medical-devices/medical-device-recalls/innova-medical-group-recalls-unauthorized-sars-cov-2-antigen-rapid-qualitative-test-risk-false-test), the most serious type of recall.

Recommendations for Test Users, Health Care Providers, and Testing Program Organizers

- 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.
- **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 the Innova test 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.

Device Description

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person had an active COVID-19 infection. The test uses 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 a 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 the FDA for distribution or use in the United States, and it has been recalled by Innova Medical Group, Inc.

Potential Risk of False Results

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person had an active COVID-19 infection using a nasal swab sample and test strip. The Innova Medical Group SARS-CoV-2 Antigen Rapid Qualitative Test, however, does **not** have authorization, clearance, or approval from the FDA. In addition, the FDA has significant concerns that the performance of the Innova Medical Group SARS-CoV-2 Antigen Rapid Qualitative Test device has 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 healthcare, long-term care, and other facilities based on false test results.
- **False-positive results** could lead to a delay in both 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.

To date, the FDA has not received reports of injuries or death associated with use of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test.

FDA Actions

The FDA has classified the recall of this test as a Class I recall (/medical-devices/medical-device-recalls/innova-medical-group-recalls-unauthorized-sars-cov-2-antigen-rapid-qualitative-test-risk-false-test), the most serious type of recall. The FDA also has issued a warning letter to Innova Medical Group, Inc. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/innova-medical-group-inc-614819-06102021)

The FDA regularly monitors the marketing of unauthorized, unapproved or uncleared tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had a problem with the Innova SARS-CoV-2 Antigen Rapid Qualitative Test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.