Potential for False Positive Results with Certain Lots of Ellume COVID-19 Home Tests Due to a Manufacturing Issue: FDA Safety Communication

November 10, 2021, Update: The FDA took additional actions related to Ellume COVID-19 Home Tests. For details, see FDA Actions below.

Date Issued: October 5, 2021

The U.S. Food and Drug Administration (FDA) is alerting test users, caregivers, health care personnel, and the public of the potential for false positive results with certain lots of the Ellume COVID-19 Home Test, due to a recently identified manufacturing issue. For these tests, a "false positive" is a test result that indicates that a person has the virus when they do not actually have it. Negative results do not appear to be affected by the manufacturing issue.

The FDA is working closely with Ellume to assess the company's additional manufacturing checks and other corrective steps to help ensure that the issue is resolved.

A complete list of affected Ellume COVID-19 Home Tests can be found on Ellume's website (http://www.ellumecovidtest.com/return) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Recommendations for Test Users and Caregivers

- Check if your Ellume COVID-19 Home Test is included in Ellume's product recall by comparing the lot number on the test carton to the lot numbers on Ellume's website (http://www.ellumecovidtest.com/return) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

- Contact your health care provider, urgent care facility, or other COVID-19 testing site and request a COVID-19 molecular diagnostic test if you received a positive test result with one of the affected lots of the Ellume COVID-19 Home Test in the last two weeks and have not already had a follow-up molecular diagnostic test to confirm the positive test result.
- Contact your health care provider, urgent care facility, or other COVID-19 testing site if:
    - You received a positive test result using one of the affected lots of the Ellume COVID-19 Home Test more than two weeks ago, and
    - You did not receive a positive result from a different COVID-19 test at the time of the original Ellume positive test result. A health care provider can help you decide what next steps you should take. You should not assume that you had COVID-19 or have immunity to COVID-19. You should continue to take recommended precautions, including vaccination, to avoid COVID-19 infection, following the Centers for Disease Control and Prevention's guidelines (https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance.html).
- If you have an unused Ellume COVID-19 Home Test from an affected lot, use the Ellume COVID-19 Home Test App or follow the directions on Ellume's website (http://www.ellumecovidtest.com/return) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to request a product replacement.

Recommendations for Health Care Personnel

Review the **Recommendations for Test Users and Caregivers** with patients who used the affected tests and received a positive result.

Test Description

The Ellume COVID-19 Home Test is an antigen test that detects proteins from the SARS-CoV-2 virus from a nasal sample in people 2 years of age and older. The Ellume COVID-19 Home Test is for people with or without COVID-19 symptoms.

The FDA issued an Emergency Use Authorization (EUA) (/media/144457/download) to permit emergency use of the Ellume COVID-19 Home Test on December 15, 2020 and granted a revision to the EUA on February 11, 2021.

FDA Actions

The FDA has classified the recall of the Ellume COVID-19 Home Test as a Class I recall (/medical-devices/medical-device-recalls/ellume-recalls-covid-19-home-test-potential-false-positive-sars-cov-2-test-results), the most serious type of recall. Ellume has identified additional affected lots since our last update on October 5, 2021, and the total of affected tests is now

around 2 million. The FDA is continuing to work with Ellume to assess the company's corrective actions, such as additional manufacturing checks and other corrective steps, to address the reason for the manufacturing issue, and to help ensure that it is resolved and will not recur.

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 Ellume COVID-19 Home 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).

Generally, as specified in a test's EUA, device manufacturers must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-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.