Recalls, Market Withdrawals, & Safety Alerts

NJLINCS Health Alert Network

Distributed by the *New Jersey Department of Health*

Subject: Public Health Recall : Certain Accula SARS-CoV-2 Tests by Mesa Biotech: Class I Recall - Due to Risk of False Positives Caused by Contamination

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Attachments: No

ISSUE: Mesa Biotech is recalling the Accula SARS-CoV-2 Test because certain lots of the test have an increased risk of giving false positive results due to contamination at the manufacturing facility.

Although there have been no reports of injuries, adverse health consequences, or death associated with the use of these affected products, false positive results could lead to further exposure of uninfected individuals to SARS-CoV-2 virus.

For more information about this recall, click on the red button **"Read Recall"** below.

BACKGROUND: The Accula SARS-CoV-2 Test is a polymerase chain reaction (PCR) test intended to detect the presence of SARS-CoV-2, the virus

that causes COVID-19, based on a nasal swab sample from patients. The sample is collected by healthcare providers or by people swabbing themselves under the guidance of a healthcare provider. This test is authorized for use in point of care (POC) settings. The sample is processed using special PCR laboratory equipment.

RECOMMENDATIONS: On April 6, 2022, Mesa Biotech issued a Product Recall letter to all customers who received the identified lots of Accula SARS-CoV-2 test kits. Customers were instructed to:

- Stop using test kits from the identified lots
- Discard or return remaining inventory from the identified lots

Customers were also asked to return a customer reply form acknowledging receipt and understanding of the issue.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.