



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: Covid-19 Rapid Antigen Tests

Today, the U.S. Food and Drug Administration (FDA) issued a safety communication warning people to stop using the Empowered Diagnostics CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test. These tests were distributed with labeling indicating they are authorized by the FDA, but neither test has been authorized, cleared, or approved by the FDA for distribution or use in the United States. The FDA is concerned about the potentially higher risk of false results when using unauthorized tests.

Empowered Diagnostics is recalling the CovClear COVID-19 Rapid Antigen Test and the ImmunoPass COVID-19 Neutralizing Antibody Rapid Test, and the FDA has identified this issue as a class I recall, the most serious type of recall.

This safety communication provides:

- Recommendations for test users, caregivers, health care personnel, and testing program organizers.
- Details on the issue and the FDA's actions to address the issue.
- Instructions for reporting problems with tests to the FDA.
- A link to the [January 28, 2022 Recall Notice](#).