November 10, 2021

COVID Point of Care Test Expiration Guidance

The California Department of Public Health (CDPH) is providing an update regarding the use of expired point of care COVID-19 tests. Some of the COVID-19 tests in California are approaching or have already passed their extended expiration dates.

Emergency Expiration Date Extension

Per the Centers for Medicare and Medicaid Services (CMS), if unexpired point of care COVID-19 tests cannot be obtained, testing programs are allowed to use expired professional CLIA waived tests if the lab director of your CLIA waived lab establishes a written policy for this use. See link to CMS guidance here: https://www.cdc.gov/csels/dls/locs/2020/cms_guidance_for_the_use_of_expired_sars-cov-2_tests.html

This emergency expiration date guidance currently does not have an end date. However, it is expected that the emergency guidance will not last indefinitely. This emergency guidance only applies when in-date supplies are unavailable. Organizations are encouraged to use the expired tests as quickly as possible. If CDPH sends notification that the emergency guidance has ended, organizations must immediately cease using the expired tests.

Quality Control (QC) Procedure

In order to use the expired tests, the control on the test must perform correctly. Additionally, CDPH is requiring users of the expired tests supplied or overseen by CDPH, to perform QC at least once every month that the expired tests are used. If your inventory of tests contains multiple lots of the tests, QC must be performed on each lot of expired tests every month. This extended expiration does not refer to the over-the-counter tests.

For questions regarding the Lab Advisory: CMS Guidance for the Use of Expired SARS CoV-2 Tests please contact CMS.