

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0646259	<b>(X3) Date Survey Completed</b>  08/31/2023
<b>Name of Provider or Supplier</b>  Hawaii Dept Of Health	<b>Street Address, City, State</b>  2725 Waimano Home Rd, Pearl City, HI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and laboratory testing personnel interview on August 30, 2023, at 1.15 p.m., it was determined that the laboratory failed to ensure that one (1) of one (1) bottle of 0.05N NaOH, all reagents, solutions, culture media, control materials, calibration materials, and other supplies were not available for use when they have exceeded their expiration date. Findings include: a. During a tour of the LRN-C laboratory, 1 of 1 bottle of 'Calibrator solvent' working solution, 0.05N NaOH, labeled with expiration date November 22, 2022, was observed in the -4 C refrigerator, and therefore available for use in patient testing. b. Based on interview of the general supervisor, the working solution is used in the preparation of calibrators for gas chromatography-mass spectrometry (GC-MS) testing of cyanide in whole blood. c. The general supervisor confirmed on August 30, 2023, at 1.15 p.m., that the 0.05N NaOH solution was available for use when it had exceeded its expiration date.</p>