

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0619844	(X3) Date Survey Completed 02/21/2025
Name of Provider or Supplier Clinical Labs Of Hawaii-Kula Hospital	Street Address, City, State 100 Keokea Place, Kula, HI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of laboratory policies and procedures, and an interview with the technical consultant on February 21, 2025 at 10:30 AM revealed the laboratory director failed to specify in writing the responsibilities and duties of the testing personnel performing the preanalytic, analytic, and post analytic phases of its patient testing to include whether supervision is required for test performance or results reporting and whether consultant or director review is required prior to reporting patient test results. Testing personnel performed an annual volume of 4,000 iSTAT routine chemistry tests, 2,000 urine microscopic examinations, 4,000 manual differential examinations, and 20,000 Sysmex pocH-100i hematology tests.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--</p>

This STANDARD is not met as evidenced by:

The surveyor's review of laboratory testing personnel competencies and an interview with the technical consultant on February 21, 2025 at 10:30 AM revealed the technical consultant failed to annually evaluate the competency of one of two testing personnel (TP #1) performing routine chemistry, urinalysis, and hematology patient testing. The technical consultant stated the 2023 and 2024 competencies for TP #1 were performed by a peer testing personnel no longer employed by the laboratory. The laboratory Competency Guidelines 602-127-2.1 delegates the responsibility of annual competency assessments to the technical consultant. The laboratory performed an annual volume of 4,000 iSTAT routine chemistry tests, 2,000 urine microscopic examinations, 4,000 manual differential examinations, and 20,000 Sysmex pocH-100i hematology tests.