Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0646234	05/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Labs Of Hawaii-Kau Hospital	1 Kamani St, Pahala, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the technical consultant (TC1) on May 30, 2025 at 9:30 AM revealed the laboratory failed to establish written policies and procedures to assess the competency of 5 of 5 testing personnel (TP1, TP2, TP3, TP4, TP6). Testing personnel performed an annual volume of 2 mycology and parasitology tests; 1001 routine chemistry; 324 urine sediment examinations; 23 endocrinology tests; and 12,363 hematology tests in 2024. The findings include: 1. TC1 stated the Lab Consultant was on the "List of Designees, Individuals authorized by the Lab Director to act on his/her behalf" policy for competency assessment activities. This policy did not list competency assessment among the activities authorized to a designee. 2. TC1 stated competency assessments to include the six required procedures were performed by laboratory testing personnel. 3. Competency records revealed testing personnel (TP1) performed July 2024 to June 2025 annual evaluations on 3 of 3 testing personnel (TP3, TP4, T6). 4. Competency records revealed testing personnel (TP2) was employed from January 2023 through June 2023. Initial training was performed by a departing testing personnel whose employment overlapped with TP2. 5. Competency records revealed testing personnel (TP6) performed the July 2023 to June 2024 annual evaluation on TP1. TP6 possesses a State of Hawaii Clinical Laboratory Personnel license exception limited to non-waived patient testing only.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

	The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: The surveyor's review of laboratory College of American Pathologists (CAP) proficiency testing records and an interview with the technical consultant (TC1) on May 30, 2025 at 10:30 AM revealed the laboratory failed to verify the accuracy of its proficiency test results reported in 2023, 2024, and 2025. The findings include: 1. TC1 stated the laboratory did not evaluate its CAP Blood Cell ID, upgraded educational challenge photograph results for 2023 BCP-C survey, specimens BCP-26 to BCP-30, 2024 BCP-A survey, specimens BCP-06 to BCP-10, 2024 BCP-B survey, specimens BCP-16 to BCP-20, 2024 BCP-C survey, specimens BCP-26 to BCP-30, and 2025 BCP-B survey, specimens BCP-16 to BCP-20. 2. The laboratory received a CAP code [27] Lack of participant or referee consensus for proficiency testing results on 2024 Clinical Microscopy CM-B specimen CMP-14, 2025 Clinical Microscopy CM-A urine sediment ID specimen USP-02, and 2025 Clinical Microscopy CM-A CSF & Body Fluid specimen CMP-09. TC1 stated the laboratory did not evaluate their responses with the CAP Participant Summary report. 3. The laboratory received a zero score for its CAP 2024 AQIS-C Critical Care Blood Gas iSTAT blood gas (PCO2, pH, PO2) performance and for its 2024 PCARM-B Point-of Care Cardiac Markers iSTAT B-Type Natriuretic Pep Troponin I, Quant performance. TC1 stated the laboratory did not verify the accuracy of these analytes after the Participant Summary was received.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: The surveyor's review of laboratory College of American Pathologists (CAP) proficiency testing records and an interview with the technical consultant (TC1) on May 30, 2025 at 10:30 AM revealed the laboratory failed to document its review the unacceptable specimen scores it received in 2023, 2024, and 2025. The findings include: 1. The laboratory received unacceptable specimen scores for 2023 CM-B Urine Sediment ID specimen CMP-15, 2024 BCP-C Blood Cell ID specimen BCP-24, and 2025 BCP-A Blood Cell ID specimen BCP-01. Documentation of laboratory review and corrective action activities undertaken were not available for the survey.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

	This STANDARD is not met as evidenced by: The surveyor's review of laboratory College of American Pathologists (CAP) proficiency testing records and an interview with the technical consultant (TC1) on May 30, 2025 at 11:00 AM revealed the laboratory failed to have general laboratory quality assessment policies and procedures to describe the corrective actions to take, resolve, and prevent the recurrence of its proficiency testing problems. The findings include: 1. The laboratory failed to verify the accuracy of its CAP proficiency results it reported in 2023, 2024, and 2025. See D tag D5215. 2. The laboratory failed to document its review of its unacceptable specimen scores in 2023, 2024, and 2025. See D tag D5221.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: The surveyor's review of laboratory policies and an interview with the technical consultant (TC1) on May 30, 2025 at 9:30 AM revealed the laboratory director failed to ensure all proficiency testing performances were reviewed and evaluated by the appropriate staff to identify problems requiring corrective action. The findings include: 1. The Lab Consultant was on the "List of Designees, Individuals authorized by the Lab Director to act on his/her behalf" policy for "PT Report Review and Sign-off" activities. 2. The laboratory failed to verify the accuracy of its proficiency test results reported in 2023, 2024, and 2025. See D tag D5215. 3. The laboratory failed to document its review of its unacceptable specimen scores in 2023, 2024, and 2025. See D tag D5221.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: The surveyor's review of laboratory College of American Pathologists (CAP) proficiency testing records and an interview with the technical consultant (TC1) on May 30, 2025 at 11:00 AM revealed the laboratory director failed to ensure an approved corrective action plan was followed for its unacceptable CAP specimen scores in 2023, 2024, and 2025. See D tag D5221.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: The surveyor's review of laboratory College of American Pathologists (CAP) proficiency testing records and an interview with the technical consultant (TC1) on May 30, 2025 at 11:00 AM revealed the laboratory director failed to establish quality assessment policies and procedures to assure the quality of its laboratory services and to identify failures as they occur. The findings include: 1. The laboratory failed to establish written policies and procedures to assess the competency of 5 of 5 testing personnel. See D tag D5209. 2. The laboratory failed to have quality assessment policies and procedures to describe the corrective actions to take, resolve, and prevent the recurrence of its proficiency testing problems. See D tag D5293.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and an interview with the technical consultant (TC1) on May 30, 2025 at 9:30 AM revealed the laboratory director failed to ensure policies and procedures were established to monitor 5 of 5 of its testing personnel performing mycology, parasitology, routine chemistry, urine sediment examinations, endocrinology,and hematology patient testing. See D tag D5209.