Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0619547	02/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Labs Of Hawaii Wailuku -Mmg	2180 Main Street 2nd Floor, Wailuku, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: The surveyor's review of laboratory quality assurance procedures and an interview with the one testing personnel on February 14, 2025 at 10:30 AM revealed the laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess, and correct analytic system problems. The laboratory performed an annual volume of 39 iSTAT Troponin I tests, 834 manual differentials, 1,586 urine microscopic examinations, and 49 post vasectomy semen examinations. The findings include: 1. The testing personnel stated documentation for 2 of 8 quality indicators listed in the laboratory PSC Quality Indicators procedure was not available fore review, e.g., Quality indicator #3 "Monitoring patient wait times and taking action to improve"and Quality indicator #4 "Evaluating yearly CLH Patient Satisfaction Surveys". 2. The testing personnel stated 4 of 16 quality indicators listed in the laboratory Appendix, Quality Assurance Indicators CLH-Wailuku-MMG Laboratory were not performed, e.g., Semiannual Abbott iSTAT: Correlation studies for Troponin I with MMMC lab, Semiannual Interlab proficiency surveys (Differential), Semiannual Interlab proficiency surveys (Urinalysis), and Microscope Annual maintenance sent to MMMC.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 quality assurance procedures and an interview with the one testing personnel on February 14, 2025 at 10:30 AM revealed the laboratory director failed to ensure that the laboratory's quality assessment program was maintained to assure the quality of the routine chemistry, urinalysis, and hematology testing services it provides. The findings include: 1. The laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess, and correct analytic system problems. See D tag D5791.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (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. This STANDARD is not met as evidenced by: The surveyor's review of laboratory policies, procedures, and records, and an interview with the one testing personnel on February 14, 2025 at 10:00 AM revealed the laboratory director failed to specify in writing the responsibilities and duties of each consultant, and testing personnel performing the preanalytic, analytic, and post analytic phases of its testing. The findings include: 1. The laboratory Form CMS-209 Laboratory Personnel Report (CLIA) lists three Technical Consultants (TC). The one testing personnel stated that TC #3 served as the interim laboratory director effective April 2024 and the laboratory director on the Form CMS-209 had not been to the laboratory in 2024 up until the current survey date. The List of Designees Annual Review sheet stated "Reason for modification: Updated Laboratory Director". TC #3 approved the modification on May 1, 2024. Documentation of the responsibilities and duties of TC #3 was not available for surveyor review. 2. Documentation of testing personnel responsibilities and duties that identifies the procedure 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 was not available for surveyor review. The one laboratory testing personnel performed an annual volume of 39 iSTAT Troponin I tests, 834 manual differentials, 1,586 urine microscopic examinations, and 49 post vasectomy semen examinations.