Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0646234	(X3) Date Survey Completed 06/16/2023
Name of Provider or Supplier Clinical Labs Of Hawaii-Kau Hospital	**Street Address, City, State** 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 interview with the laboratory director and general supervisor on 06/16/2023 at 10:00 AM revealed the laboratory failed to follow its written policies and procedures to assess the competency of 3 of 3 testing personnel and 1 general supervisor in 2021 and 2022. The laboratory performs an annual volume of 1231 Chemistry tests, 3989 Hematology tests, 10 General Immunology tests and 2 Mycology tests. The findings include: 1. The laboratory's Competency Testing procedure, SOP-QA-001, Rev 1. 04/08/05 lists the following competency assessment forms for use: "Form 001: Direct Observation Competency form Form 002: Proficiency/Previously Analyzed Sample Competency form Form 003: Worksheet/QC/Maintenance Record Review Competency Form Form 004: Phlebotomy/Processing Direct Observation Form Form 005: Accessioning/Processing Direct Observation Form" 5 of 5 forms for each testing personnel and general supervisor were not available for surveyor review. 2. A review of Form 001: Direct Observation Competency form revealed KOH examinations and Sysmex Hematology Analyzer testing competencies were not included for assessment.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: The surveyor's review of equipment and instrument maintenance records, and interview with the general supervisor on 06/16/2023 at 10:30 AM revealed the laboratory failed to perform annual maintenance on its Zeiss Model STD20 microscope, SN 380078 in 2020, 2021, and 2022. The laboratory performs an annual volume of 400 urine microscopic examinations, 696 manual differentials, and 2 KOH examinations.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 equipment and instrument maintenance records, and interview with the general supervisor on 06/16/2023 at 10:30 AM revealed the laboratory director failed to ensure the laboratory established a maintenance protocol for its Zeiss Model STD20 microscope, SN 380078 to ensure the quality of its chemistry, hematology, and mycology testing. See D tag D5433.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 interview with the laboratory director and general supervisor on 06/16/2023 at 10:00 AM revealed the laboratory director failed to ensure policies and procedures are established for monitoring individuals conducting its chemistry, hematology, general immunology, and mycology testing to assure they maintain their competency and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D tag D5209.