Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0646234	01/05/2022
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**
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control records, an interview with testing personnel and confirmation by Technical Consultant 2 on 01/05/2022 at 11:00 am, it was determined that the laboratory failed to monitor the accuracy and precision of its Sysmex hematology testing process by following established control procedures. The findings include: 1. Laboratory quality management procedure, CLHB.QM. 06.3010.0909.2 states "print the L-J (Levey-Jennings) charts for all the levels and parameters in the case of a CBC. Look for evidence of shifts and trends or other QC rule violations". The testing personnel confirmed on 01/05/2022 at 10:45 am that Sysmex control L-J charts were not printed and reviewed for shifts, trends or other QC rule violations. 2. Laboratory quality management procedure, CLHB.QM. 06.3010.0909.2 instructions for "Saving Levey-Jennings Graphs to the CLH Intranet Shared Folder" state "Review Levey-Jennings charts at the end of each lot or monthly". "The tech at the site should go to that saved file and enter relevant comments such as, when calibrations wre performed and reagent lot changes, major maintenance or troubleshooting that was performed if not already indicated.

	Investigate shifts and trends." The testing personnel confirmed on 01/05/2022 at 10:45 am that monthly Sysmex L-J charts were not generated and saved to the intranet shared folder for review. 3. Laboratory quality management procedure, CLHB.QM. 06.3010.0909.2 states in the section, "Supervisor/Lab Manager/Laboratory Director /Designee Review", "Review each Levey-Jennings chart. Enter any relevant comments and indicate your review by adding your name and a date/time stamp". The Technical Consultant 2 confirmed that Sysmex L-J chart review by the Supervisor /Laboratory Director/Designee was not performed. 4. The laboratory performed 5880 hematology tests in 2021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control records, an interview with testing personnel and confirmation by Technical Consultant 2 on 01/05/2022 at 11:00 am, it was determined that the laboratory director failed to ensure that its established quality control program was maintained to assure the quality of the hematology laboratory services provided. See CFR 493.141256(a)(B)(C)(G), D tag D 5441