Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0619602	05/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Labs Of Hawaii-Lanai Community Hospital	628 7th St, Lanai City, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of records and interview with the laboratory director and technical consultant on 5/28/19, the laboratory failed to retain quality control records of their prothrombin time/ INR controls for at least 2 years. Findings included: a. The laboratory tested two levels of control material each month for the prothrombin time/ INR tests. Their printout for prothrombin/INR control levels showed that control level 1 lot# 281097 and control level 2 lot# 291096 were run on 4/5/19. At the time of the survey, the manufacturer's assay information was not available for these two controls. b. The laboratory tested and reported prothrombin time and INR test results on approximately 36 patients a year.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following

	occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the lack of records and interview of the laboratory director and technical consultant on 5/28/19, the laboratory failed to perform and document calibration procedures on their troponin test at least every 6 months. Findings included: The laboratory performed and reported approximately 50 troponin test results on patients each year. Laboratory records showed calibration verification was done on 5/23/19 and 10/22/18. There was no documentation of calibration performed before 10/22/18.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on interview of the laboratory director and technical consultant and review of control records on 5/28/19, the laboratory failed to document corrective action taken when results of their prothrombin/ INR controls failed to meet the laboratory's criteria for acceptability. Findings included: a. The laboratory tested two levels of controls each month for the prothrombin time/ INR test performed on the iStat system. Their printout for prothrombin/INR control levels showed that control level 1 lot# 281097 and control level 2 lot# 291096 were run on 4/5/19. The expiration date for lot # 281097 was entered as 1/31/19 and the expiration date for lot# 291096 was 12/31/18. According to the technical consultant, these lot numbers and expiration dates were incorrect and the two levels of control run on 4/5/19 had not expired. At the time of the survey, there was no documentation of action taken to correct the laboratory's records of the lot numbers and expiration dates on these two controls. b. The laboratory tested and reported prothrombin time and INR test results on approximately 36 patients a year.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of records and interview of the laboratory director and technical consultant on 5/28/19, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in their prothrombin time/ INR and troponin tests. Findings included. a. The laboratory failed to perform and document calibration procedures on their troponin test at least every 6 months. See D5439. b. the laboratory failed to document corrective action taken when results of their prothrombin/ INR controls failed to meet the laboratory's criteria for acceptability. See D5783.