Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0619844	04/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Labs Of Hawaii-Kula Hospital	100 Keokea Place, Kula, 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
D2088	ROUTINE CHEMISTRY CFR(s): 493.841(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a review of CAP Critical Care Blood Gas, i-STAT proficiency testing records and an interview with the General Supervisor on 04/26/2023 at 09:00 AM, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent. The laboratory performed an annual volume of 10,056 tests. The findings include: 1. The laboratory received a 0% score for its unsatisfactory performance in the second AQI-B testing event of 2022. 2. The General Supervisor confirmed the testing personnel failed to test 5 of 5 samples (AQI-06, AQI-07, AQI-08, AQI-09, AQI-10) for chloride, potassium, sodium, creatinine, glucose and urea nitrogen (BUN) and 3 of 5 samples (AQI-08, AQI-09, AQI-10) for lactate.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by:

	Based on a review of CAP Critical Care Blood Gas i-STAT proficiency testing records and an interview with the General Supervisor on 04/26/2023 at 09:00 AM, it was determined that the laboratory failed to undertake appropriate training and employ the technical assistance necessary to correct its unsatisfactory performance. The laboratory performed an annual volume of 10,056 tests. The findings include: 1. The laboratory received a 0% score for its performance in the second AQI-B testing event of 2022. 2. The General Supervisor stated the testing personnel testing the proficiency survey samples was not aware of what tests should be performed. The General Supervisor confirmed the individual left after 2 months of employment. See D tag D2088. 3. Documentation of corrective action and monitoring activities were not available for review.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of CAP Hematology Auto Differentials proficiency testing records and an interview with the General Supervisor on 04/26/2023 at 09:00 AM, it was determined that the laboratory failed to undertake remedial action for its unacceptable platelet count performance in the second FH1 testing event of 2022. The findings include: 1. The laboratory reported a platelet count of 130 x 10E9/L for Specimen FH1-08. The limits of acceptability were 48 to 81 x 10E9/L. 2. The General Supervisor stated that remedial action was initiated but not completed or documented.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records, direct observation and interviews with the General Supervisor and testing personnel on 04/26/2023 at 09:00 AM and 10:00 AM respectively, it was determined that the laboratory failed to establish and follow written policies and procedures tor an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems requirements. The findings include: 1. The laboratory failed to undertake appropriate training and employ the technical assistance necessary to correct its unsatisfactory performance in the second CAP AQI testing event of 2022. See D tag D2094. 2. The laboratory failed to undertake remedial action for its unacceptable platelet count performance in the second FH1 testing event of 2022. See D tag D2128. 3. The laboratory failed to label

	the hematology reagents it used to stain its manual differential blood smears. See D tag D5415.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and an interview with 2 of 2 testing personnel on 04/26 /2023 at 10:00 AM, it was determined that the laboratory failed to label the hematology reagents it used to stain its manual differential blood smears. The laboratory stained an annual volume of 4020 blood smears. The findings include: 1. 3 of 3 Coplin jars containing reagents were available for use on the laboratory counter. The jars were not labeled with their contents, storage requirements, and expiration dates. 2. Testing personnel stated the first jar contained Volusol Buffered Wright-Giemsa stain. The stain was poured from a stock bottle, lot VSS383, expiration date 08 /31/2023 although the pour off date could not be confirmed. The second and third jars contained rinse water. 3. The General Supervisor stated during an interview on 04/26 /2023 at 10:15 AM that laboratory policy did not provide instructions on labeling these reagents to include how often to change them.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of CAP proficiency testing records and an interview with the General Supervisor on 04/26/2023 at 09:30 AM, it was determined that the laboratory director failed to ensure that all proficiency testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: 1. The laboratory failed to undertake appropriate training and employ the technical assistance necessary to correct its unsatisfactory performance in the second CAP AQI testing event of 2022. See D tag D2094. 2. The laboratory failed to undertake remedial action for its unacceptable platelet count performance in the second FH1 testing event of 2022. See D tag D2128.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on direct observation and an interview with 2 of 2 testing personnel on 04/26 /2023 at 10:00 AM, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance. The findings include: 1. The laboratory failed to label the hematology reagents it used to stain its manual differential blood smears. See D tag D5415.