Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0619844	09/17/2021
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
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency test records and confirmation by the testing personnel on 09/17/2021 at 09:30 am, it was determined that the laboratory failed to return its 2020 College of American Pathologists (CAP) Critical Care Aqueous Blood Gas (AQI) proficiency testing results within the time frame specified by the program. The findings include: 1. The laboratory obtained a score of 0 for its performance in the 2020 AQI-B testing event. This survey includes chloride, creatinine, glucose, potassium, sodium and blood urea nitrogen (BUN). 2. The testing personnel stated that proficiency test results are forwarded to Maui Memorial Hospital from Clinical Labs of Hawaii Kula Hospital for review and submission before the survey due date. 3. The Proficiency Testing Procedure states "Mail, fax or enter the results on-line well within the allotted time of 10 working days from the date of receipt. If submitting by fax, check the fax verification form to ensure that the transmission was accepted. Retain the fax verification form with PT documentation". If submitting results on-line, "print copy of entered results". "Review all on-line entries, compare to hard copy, and make corrections if necessary". Documentation of fax or on-line activity was not available for review. The testing personnel stated that the laboratory did not track the sendout to and receipt of its proficiency test results at MMH. 4. The laboratory performed 356 Abbott iStat Chem 8+ panels in 2021.
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 laboratory proficiency test records and an interview with the testing personnel on 09/17/2021 at 09:45 am, it was determined that the laboratory failed to undertake the appropriate remedial actions to include the appropriate training and employing the technical assistance necessary to correct problems associated with its CAP routine chemistry proficiency testing failures. The findings include: 1. The laboratory obtained an unacceptable grade for its BUN result on sample AQI-07 in the 2021 AQI-B testing event. The laboratory reported 57.0 which had a SDI of -17.6 when compared to its peer group. 2. The laboratory Proficiency Testing Procedure states: "The supervisor, lab manager, and laboratory director/pathologist should all participate in the review of survey results. The reviews should be completed within 30 days of the receipt of the results. Submit all investigation and follow-up reports for unacceptable, ungraded, or failed surveys to the laboratory director/pathologist for review/approval of actions taken. In the case of unacceptable PT results, send a copy of the evaluation to CLH Quality Improvement Manager." Documentation of each of these tasks was not available for review. 3. The Proficiency Testing Procedure states: "Communicate all pertinent corrective actions to technical staff and retrain as needed. Document the retraining." The testing personnel stated on 09/17/2021 at 10:00 am that retraining activities were not performed for this survey. 4. The laboratory performed 356 BUN tests in 2021.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and an interview with the testing personnel on 09/17/2021 at 09:50 am, it was determined that the laboratory failed to attain a score of at least 80% of acceptable responses for its 2020 CAP FH1-B Cell identification/flow differential proficiency testing event. The findings include: 1. The laboratory obtained a unsatisfactory score of 60% for two of five FH1-B proficiency testing specimens in 2020. a. The laboratory reported an unacceptable identification of neutrophil, metamyelocyte for specimen BCP-11. The intended result was monocyte. b. The laboratory reported an unacceptable identification of microcyte with increased pallor for specimen BCP-13. The intended result was erythrocyte normal.
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 laboratory proficiency testing records and confirmation by the testing personnel on 09/17/2021 at 09:45 am, it was determined that the laboratory failed to undertake the appropriate training and technical assistance necessary to correct problems associated with its unsatisfactory 2020 CAP FH1-B Cell identification/flow differential proficiency testing score. The findings include: 1. The laboratory obtained a unsatisfactory score of 60% for two of five FH1-B proficiency testing specimens in 2020. 2. The laboratory Proficiency Testing Procedure states: "The supervisor, lab manager, and laboratory director/pathologist should all participate in the review of survey results. The reviews should be completed within 30 days of the receipt of the results. submit all investigation and follow-up reports for unacceptable, ungraded, or failed surveys to the laboratory director/pathologist for review/approval of actions taken. In the case of unacceptable PT results, send a copy of the evaluation to CLH Quality Improvement Manager." Documentation of each of these tasks was not available for review. 3. The Proficiency Testing Procedure states: "Communicate all pertinent corrective actions to technical staff and retrain as needed. Document the retraining." The testing personnel stated that retraining activities were not performed for this survey.
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: Based on an interview with the testing personnel on 09/17/2021 at 09:30 and confirmation at 10:00 am by the Technical Consultant, it was determined that the laboratory failed to follow its written policies and procedures to assess employee and consultant competency. The findings include: 1. The laboratory Competency Guidelines procedure states "It is the manager's responsibility to ensure all technical staff are evaluated for competency during orientation upon hire, 6 months after hire, and annually thereafter. All competency evaluations must be documented. The departments to be assessed are: Phlebotomy, Accessioning, Processing, Hematology, Chemistry, and Urinalysis." The Technical Consultant confirmed that a 2020 annual competency evaluation was not performed on the testing personnel responsible for daily hematology, routine chemistry and urine microscopic analyses. 2. The Technical Consultant confirmed that a 2020 annual consultant competency evaluation was not performed. 3. The laboratory performed 356 iStat Chem 8+ panels, 356 iStat troponin tests, chemistry, 3639 manual differentials, 1747 urine microscopic's in 2021.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

	The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and confirmation by the testing personnel on 09/17/2021 at 10:00 am, it was determined that the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. The findings include: 1. The laboratory was assigned code [26], "result outside the method /instrument reportable range" for its 2021 CAP AQI-B creatinine result on specimen AQI-06. Laboratory verification of the accuracy of this PT result against CAP participant summary results was not performed. 2. The laboratory was assigned code [27], "lack of participant or refer consensus" for its 2020 CAP CM-A urine microscopic result on specimen CMP-04. The laboratory reported calcium oxalate crystal . The intended response reported by 74.6% participants was hippuric acid. Laboratory verification of the accuracy of this PT result against CAP participant summary results was not perfromed. 3. The laboratory was assigned a zero score for non participation in the 2020 AQI-B routine chemistry testing event. Laboratory verification of the accuracy of its iStat Chem 8+ and troponin test results against CAP participant summary results was not perfromed. 4. The laboratory performed 356 creatinine tests, 1747 urine microscopy procedures and 356 iStat Chem 8+ tests in 2021.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on an interview and confirmation by the testing personnel on 09/17/2021 at 09: 00 am, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the preanalytical systems, The findings include: 1. The laboratory collects, processes and sends out non-stat/routine patient specimens for testing at the Maui Memorial Hospital (MMH) laboratory. The testing personnel stated that the Kula Hospital laboratory did not track the patient specimens it referred from the time of collection to the time of receipt by MMH. Logsheets to include requisitions were not available for review. The testing personnel stated that the status of sendout specimens was checked when an ordering physician or floor inquired about a delay in receiving patient test results. Testing personnel stated that they had not participated in assessment activities related to test requests, specimen submission, handling and referral.
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: Based on a review of laboratory maintenance records and confirmation by the testing personnel on 09/17/2021 at 08:45 am, it was determined that the laboratory failed to establish and follow a maintenance protocol that ensured the performance of its Olympus CX31 microscope SN 4H13492 that is necessary for accurate and reliable test results. The findings include: 1. The testing personnel stated that the laboratory did not have a maintenance log for the microscope that is used to perform urine microscopics and manual differentials. 2. Laboratory records showed the last vendor maintenance visit occurred on 08/21/2019. 3. The laboratory performed 1747 urine microscopic amalyses and 3639 manual differentials in 2021.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the testing personnel on 09/17/2021 at 09:30 am, it was determined that the laboratory failed to review and document the effectivenes of the corrective actions it took to respond to the Abbott Urgent Product Memo it received on January 15, 2020. The findings include: 1. A January 20, 2020 Clinical Labs of Hawaii (CLH) "Memo: Urgent Product Corrective Action Issued by Abbott Point of Care, Inc." was sent to Kula Hospital. The memo stated: "On January 15, 2020, CLH received an urgent product corrective action notice from Abbott concerning iSTAT Point of Care testing. The notification specified that certain testing cartridges have not been FDA approved. Products affected at your facility: Chem 8+ (Blue) cartridges include testing for sodium, potassium, chloride, BUN, ionized calcium, TCO2, glucose, creatinine and hematocrit; CG4+ (Blue) cartridges include testing for pH, pCO2, pO2 and lactate; and G3+ (Blue) cartridges include testing for pH, PO2, pCO2, TCO2, HCO3, BE, and sO2." CLH notified Kula Hospital that upon receipt of this memo,"the conditions for utilization of this non-FDA cleared assay have been met by CLH. We are working to transition testing to an alternate method and will provide updates as they become available. Please contact your hospital laboratory manager or laboratory medical director should you have any questions". 2. Documentation of the conditions of utilization for the non-FDA cleared assay, the status of the transition to an alternate method to include updates and a

	review or patient test results affected by the non-FDA cleared cartridges was not available for review. 3. The laboratory performed 356 iStat Chem 8+ panels and 356 troponin tests in 2021.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and confirmation by the testing personnel on 09/17/2021 at 09:30 am, it was determined that the Laboratory Director failed to ensure its College of American Pathologists (CAP) proficiency testing results were returned within the timeframe established by the program. The findings include: 1. The laboratory obtained a score of 0 for its performance in the second Critical Care Aqueous Blood Gas (AI-B) testing event in 2020. This survey includes the following routine chemistry tests: chloride, creatinine, glucose,potassium, sodium and blood urea nitrogen (BUN). See CFR 493.841(d) 2. The laboratory performed 356 iStat Chem 8+ panels in 2021.
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 laboratory proficiency testing records and interviews with and confirmations by testing personnel on 09/17/2021 at 09:45 am and 10:00 am respectively, 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 problems that require corrective action. The findings include: 1. The laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. a. The laboratory was assigned code [26], "result outside the method/instrument reportable range" for its 2021 CAP AQI-B creatinine result on specimen AQI-06. b. The laboratory was assigned code [27], "lack of participant or refer consensus" for its 2020 CAP CM-A urine microscopic result on specimen CMP-04. c. The laboratory was assigned a zero score for nonparticipation in the AQI-B 2020 routine chemistry testing event. d. Laboratory verification of the accuracy of its iStat Chem 8+, troponin and urine microscopic test results was not performed. See

	CFR 493.1236(b)(2), D tag D5215 2. The laboratory performed 356 creatinine tests, 356 iStat Chem 8+ panels 1747 urine microscopic analyses in 2021.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing records and confirmation by the testing personnel on 09/17/2021 at 09:45 am, it was determined that the Laboratory Director failed to ensure that an approved corrective action plan is followed when any unacceptable or unsatisfactory proficiency testing scores are received. The findings include: 1. The laboratory failed to undertake the appropriate training and technical assistance necessary to correct problems associated with a 60% unsatisfactory score it received for its 2020 CAP FH1-B Cell identification/flow differential survey. See CFR 493.1407(e)(4)(vi), D tag D2128 2. The laboratory failed to undertake the appropriate remedial actions to include the appropriate training and employing the technical assistance necessary to correct problems associated with an unacceptable BUN grade it received for its 2021 CAP AQI-B Critical Care Aqueous Blood Gas survey. See CFR 493.841(e), D tag D2094 3. The laboratory Proficiency Testing Procedure, Section Laboratory Director/Pathologist Review states: "For failed or unacceptable performance, the laboratory director or other approved reviewer should: Evaluate the conclusions reached for the failures; Determine if patient samples may have been affected and to what degree; Indicate if patient retesting or further lookback is required; Determine if corrective action is appropriate and complete; Ensure information gleaned from thee reviews is shared with all staff, as appropriate. Documentation of these activities was not available for review. 4. The laboratory performed 3639 manual differentials and 356 BUN tests in 2021.
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 a review of laboratory maintenance recods and confirmation by the testing personnel on 09/17/2021 at 08:45 am, it was determined that the Laboratory Director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings include: 1. The laboratory failed to establish and follow a maintenance protocol that ensured the performance of its

	Olympus CX31 microscope SN 4H13492 that is used to perform urine microscopics and manual differentials. See CFR 493.1254(b)(1), D tag D5433 2. The laboratory performed 1747 urine microscopic amalyses and 3639 manual differentials in 2021.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the testing personnel on 09/17/2021 at 09:30 am, it was determined that the Technical Consultant failed to document the effectiveness of the remedial actions it took in response to the Abbott Urgent Product Memo it received on January 15, 2020. See CFR 493.1289(b)(c), D tag D5793
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: Based on an interview with the testing personnel on 09/17/2021 at 09:30 am and confirmation at 10:00 am by the Technical Consultant, it was determined that the Laboratory Director failed to follow its written policies and procedures to monitor individuals who conduct preanalytical, analytical and post analytical phases of testing to ensure that they are competent and maintain their competency to process specimens, perform test procedures and report results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings include: 1. The laboratory Competency Guidelines procedure states "It is the manager's responsibility to ensure all technical staff are evaluated for competency during orientation upon hire, 6 months after hire, and annually thereafter. All competency evaluations must be documented. The departments to be assessed are: Phlebotomy, Accessioning, Processing, Hematology, Chemistry, and Urinalysis." 2. The Technical Consultant confirmed that a 2020 annual competency evaluation was not performed on the testing individual responsible for chemistry, hematology and urine microscopic testing. 3. The Technical Consultant confirmed that a 2020 annual consultant competency evaluation was not performed. 4. The laboratory performed 356 iStat Chem 8+ panels, 356 iStat troponin tests, 3639 manual differentials, and 1747 urine microscopic analyses in 2021.