Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D2158485	07/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Of Waikiki	120 Kaiulani Avenue #Kw 10 And 11, Honolulu, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the laboratory director on 07/26/2023 at 9:30 AM, it was revealed the laboratory failed to have the current laboratory director approve, sign and date its Beckman DxH520 hematology instrument manufacturer procedure manual and its Quality Assessment Plan procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of laboratory temperature records and an interview with the laboratory director on 07/26/2023 at 10:30 AM, it was revealed the laboratory failed to store Beckman DxH520 hematology reagents according to the manufacturer's instruction. The laboratory annually performs 21,900 hematology tests. The findings

	include: 1. The laboratory acceptable room temperature range is 15 to 25 degrees Centigrade (C). Beckman manufacturer's instruction states the DxH520 Series Lyse reagent storage temperature range is 4 to 25 degrees C and the DxH520 Series Cleaner storage temperature range is 2 to 25 degrees C. 2. Temperatures in 2022 exceeded 25 degrees C on one of 31 days in July, two of 31 days in August, three of 30 days in September and two of 31 days in October. 3. Temperatures in 2023 exceeded 25 degrees C on one of 31 days in January, six of 31 days in May and eight of 31 days in June. 4. Temperature records for March 2023 and April 2023 were unavailable for review.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of Beckman DxH520 hematology instrument manufacturer's manual and interview with testing personnel #1 and the laboratory director on 07/26 /2023 at 11:00 AM, it was revealed that the laboratory failed to establish accuracy performance specifications for the Basophil percent values and adult reference ranges reported on patient automated differentials. The laboratory annually performs 21,900 automated differentials. The findings include: 1. The DxH520 manufacturer's manual states: "All numerical result reports for Basophil count and percent values must be reflexed for manual microscopy or followed up for additional tasting based on the laboratory's Standard Operating Procedure (SOP). The laboratory does not report out Basophils on their patient reports." 2. Testing personnel #1 states its the laboratory practice to transcribe Basophil percent values from DxH520 instrument printouts into patient reports in the laboratory information system (LIS). The surveyor confirmed this practice by observation of a LIS hematology report on a patient tested on 07/25 /2023. 3. The laboratory director states the laboratory did not establish Basophil performance specifications before reporting percent values and adult reference ranges.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of Cepheid GeneXpert manufacturer's manual and an interview with the laboratory director on 07/26/2023 at 10:30 AM, it was revealed the

	laboratory failed to perform and document required maintenance on its GeneXpert instrument SN740410. The laboratory annually performs 5,110 virology, 1,460 bacteriology and 730 parasitology tests. The findings include: 1. Monthly maintenance activities, Archive tests, Purge tests and Replace fan filters were not performed in August 2022 and October 2022. 2. GeneXpert System Maintenance Logs documenting daily, weekly, monthly, and quarterly activities for March 2023 and April 2023 were unavailable for review.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of laboratory temperature records and an interview with the laboratory director on 07/26/2023 at 10:30 AM, it was revealed the laboratory failed to document all corrective actions taken to ensure the proper storage of Beckman DxH520 hematology reagents, DxH520 Series Lyse and DxH520 Series Cleaner. See D tag D5413
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 laboratory records, procedure manuals, and interview with testing personnel #1 and the laboratory director on 07/26/2023 between 9:00 AM and 11:00 AM, it was revealed that the laboratory failed to follow its Quality Assessment Plan, Indicators of Quality, Analytic Phase procedure and Review of Results-Manual Review of Results, Routine Testing procedure. The laboratory annually performs 5,110 virology, 1,460 bacteriology, 730 parasitology, and 21,900 hematology tests. The findings include: The Quality Assessment Plan, Indicators of Quality, Analytic Phase procedure states "Quality Indicators for this facility have been defined as, but not limited to: Analytic Phase: a. Review and update of procedure manual; b. Monitoring supply and storage of reagents, test equipment, instruments, materials; c. Instruments, with verifiation of calibration, quality control and maintenance; d. Review of reference ranges; e. Test records". 1. The laboratory failed to have the current laboratory director approve, sign and date its Beckman DxH520 manufacturer procedure manual and its Quality Assessment Plan procedure. See D tag D5407 2. The laboratory failed to store Beckman DxH520 hematology reagents according to manufacturer's instruction. See D tag D5413 3. The laboratory failed to document corrective actions taken to ensure the proper storage of Beckman DxH520 hematology reagents. See D tag D5785 4. The laboratory failed to establish accuracy performance specifications for the Basophil percent values and adult reference ranges reported on patient automated differentials. Se D tag D5423 5. The laboratory failed to perform

	and document required maintenance on its Cepheid GeneXpert instrument SN740410. See D tag D5429 The Review of Results-Manual Review of Results, Routine Testing procedure states: "The individual instrument (Beckman DxH520) will identify "low" or "high" results. In addition, the instrument will individually display each result that falls outside the reference range, and display a complete listing of data including reference ranges before the testing personnel verifies the results. Testing personnel will review results and complete" a five step patient data analysis. 1. Testing personnel #1 states the patient data analysis described in the procedure is not performed prior to releasing patient results.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with testing personnel #1 on 07/26/2023 at 11:00 AM, it was revealed the laboratory failed to maintain patient test report information such that it is readily available to the CMS surveyor during the onsite survey. A patient survey sample could not be provided upon surveyor request. The testing personnel states the laboratory manual Daily Laboratory Specimen Log is not in use. The testing personnel also states a daily patient log to include tests ordered and performed cannot be printed from the LIS..
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of laboratory records, procedure manuals, and an interview with testing personnel #1 07/26/2023 between 9:00 AM and 11:00 AM, it was revealed the laboratory failed to follow its Quality Assessment Plan, Indicators of Quality, Post-Analytic Phase procedure and Review of Results-Manual, 2. Reporting of Results procedure. The laboratory annually reports 29,200 bacteriology, parasitology, virology and hematology tests. The findings include: 1. The Quality Assessment Plan, Indicators of Quality, Post-Analytic Phase procedure states, "Quality Indicators for this facility have been defined as, but not limited to: Post-Analytic Phase: a. Result reporting, verification of records and procedure for corrected reports; b. Documentation and notification of critical values and turn-around time evaluation". Testing personnel #1 states these activities were not performed. Referenced quality assurance forms, Test Tracking/Result Reporting/Chart Audit, LIS and EMR Accuracy, and Result Storage Assessments were not in use. 2. The Review of Results-Manual, 2. Reporting of Results procedure states, "The test report will contain the following elements: 3) Patient demographics: a) Full Name, b) Unique identifier, c) Date of birth, d) Sex, e) Pertinent clinical information to ensure accurate interpretation (e.g. fasting) i. Specimen information; Date and time of collection, Date tested and reported; ii. Ordering provider name". Surveyor observation of a LIS hematology

	report on a patient tested on 07/25/2023 revealed it did not contain the patient's sex, specimen date and time of collection, date reported, and ordering provider name information.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of Beckman DxH520 manufacturer's manual and interview with testing personnel #1 and the laboratory director on 07/26/2023 at 11:00 AM, it was revealed that the laboratory director failed to ensure that verification procedures were established for the Basophil percent values and adult reference ranges it reported on patient automated differentials. See D tag D5423
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records and procedures, and interview with testing personnel #1 and the laboratory director on 07/26/2023 between 9:30 AM and 11:00 AM, it was revealed the laboratory director failed to ensure its testing personnel maintained established analytic and post analytic quality assessment program activities. See D tags D5791 and D5891
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on a review of laboratory personnel records and an interview with the laboratory director on 07/26/2023 at 11:30 AM, it was revealed that the laboratory director failed to employ clinical laboratory personnel licensed by the sate of Hawaii to perform moderate complexity bacteriology, parasitology, virology and hematology testing. See D tag D6064
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with the laboratory director on 07/26/2023 at 9:30 AM, it was revealed the laboratory director failed to ensure an approved Beckman DxH520 manufacturer procedure manual and an approved Quality Assessment Plan procedure was available to testing personnel. See D tag D5407
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of laboratory personnel records and interview with testing personnel #1 and the laboratory director, it was revealed the laboratory technical consultant failed to assess the competency of seven or seven testing personnel following the six CLIA required competency assessment criteria. The findings include: 1. The Technical Consultant Job Description states "The technical consultant will be responsible for Assessment and maintenance of competence of all individuals who conduct pre-analytical, analytical, and post analytical phases of testing and identify necessity for remedial training or continuing education to improve of enhance skills". 2. The Laboratory Personnel Requirements and Responsibilities procedure states the technical consultant "evaluates and documents the performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter." 3. The laboratory consultant provides remote oversight of the laboratory. A former nurse supervisor performed and documented the required competency assessments on seven or seven testing personnel: Testing personnel #1 Annual assessment (date of hire 05/19/2019) Testing personnel #2 Initial, six months, annual assessment (date of hire 02/27/2022) Testing personnel #3 Initial, six months, annual assessment (date of hire 03/20/2021) Testing personnel #4 Annual assessment (date of hire 06/30/2020) Testing personnel #5 Initial, six months,

	annual assessment (date of hire 01/18/2022) Testing personnel #6 Initial, six months assessment (date of hire 07/22/2022) Testing personnel #7 Annual assessment (date of hire 12/17/2018)
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on a review of an Employee Roster Report and laboratory personnel records, and an interview with the laboratory director on 07/26/2023 at 11:30 AM, it was revealed that seven of seven testing personnel performing moderate complexity bacteriology, parasitology, virology and hematology testing did not possess a current Hawaii State Laboratory Medical Laboratory Technologist or Medical Laboratory Technician or Clinical Laboratory Specialist license issued by the sate of Hawaii, where such licensing is required. The laboratory director confirms two licensed registered nurses (testing personnel #1 and #4) and four medical assistants (testing personnel #2, #3, #5 and #6) are employed as testing personnel. The education background of testing personnel #7 could not be confirmed. Testing personnel annually perform 5,110 virology, 1,460 bacteriology, 730 parasitology and 21,900 hematology tests.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on a review of Cepheid GeneXpert manufacturer's manual and an interview with the laboratory director on 07/26/2023 at 10:30 AM, it was revealed laboratory testing personnel failed to perform maintenance procedures on its GeneXpert instrument SN740410 as required. See D tag D5429