Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D2158485	07/28/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing record review and technical consultant and laboratory personnel interviews on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to enroll in an HHS approved proficiency testing program that meets the criteria in subpart I of this part for each test the laboratory using the Cepheid GeneXpert instrument. The findings include: a. The laboratory performed patient Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae and HIV testing on its Cepheid GeneXpert instrument. b. The Technical Consultant stated that the laboratory was not enrolled in an HHS approved proficiency testing program for any of the tests performed using the Cepheid GeneXpert instrument. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 61 patient tests per month of each of the following tests: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: General Laboratory Systems was not met. It was determined that the laboratory failed to follow its written policies and procedures to assess employee and consultant competency (see D5209), and have a mechanism to verify the accuracy of its patient COVID-19 test at least twice annually (see D5217).
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 laboratory written protocol record review and and laboratory personnel interviews on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to follow its written policies and procedures to assess employee and consultant competency. The findings include: a. The laboratory's Quality Assessment Plan listed "personnel qualifications, training and performance evaluation" as a general quality indicator for the facility. On July 28, 2021, the day of the onsite survey, the laboratory maintained no documentation of personnel qualifications for 5 of 5 Cepheid GeneXpert testing personnel to meet this laboratory general quality indicator. b. The laboratory maintained a testing personnel "Competency Checklist" form to be used for the laboratory's initial, 6-month, and annual testing personnel competency evaluations. Instructions on the use of this form stated: "Document by dating and initialing each item at the time of evaluation that employee has shown competency and complete the method of review to include information on specific tests and records reviewed." For 5 of 5 of the laboratory's Cepheid GeneXpert testing personnel, the laboratory maintained no documentation to indicate that the laboratory's "Competency Checklist" form for an "initial direct observation of test performance, monitor results recording and reporting, review of worksheets, QC [quality control], PT [profieicncy testing] and maintenance records reporting, assessment of test performance records and assessment of problem solving reporting" had been completed. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests using the Cepheid GeneXpert instrument: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on laboratory written protocols record review and laboratory personnel interviews on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to have a mechanism to verify the accuracy of its patient COVID-19 test, which is not included in subpart I of this part, at least twice annually. The findings include: a. It was the practice of the laboratory to perform patient COVID-19 testing using the Cepheid GeneXpert instrument and a laboratory modified CareStart COVID-19 Antigen Rapid Diagnostic Test. b. The laboratory maintained no mechanism to verify the accuracy of the the laboratory's Cepheid GeneXpert COVID-19 test system and the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test at least twice annually, and had not done so since the laboratory began using these test systems. c. According to laboratory personnel, the laboratory began using the Cepheid GeneXpert instrument in April 2021 and performed an average of 304 patent COVID-19 tests per month. In addition, in May 2021, the laboratory performed approximately 100,000 patient COVID-19 tests using the modified CareStart COVID-19 Antigen Rapid Diagnostic Test.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Preanaltyic Systems was not met. The laboratory failed to have written or electronic requests for patient testing from an authorized person (see D5301), and establish written policies and procedures for the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test for specimen collection (see D5311).
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on laboratory test requisitions record review and laboratory personnel interview on July 28, 2021 at 10:30 am, it was determined that the laboratory failed to have written or electronic requests for patient testing from an authorized person. The findings include: a. It was the practice of the laboratory to perform patient testing using the laboratory's Cepheid GeneXpert instrument for five physicians. b. Laboratory personnel stated that documentation of the ordering physician could be

	found in the patient's medical records. However, upon request for copies of patient test requisitions, the laboratory could only provide test requisitions originating from 2 of the 5 physicians even though all 5 physicians had ordered patient testing using the laboratory's Cepheid GeneXpert instrument. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests using the Cepheid GeneXpert instrument: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory written protocol record review and laboratory personnel interviews on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to establish written policies and procedures for the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test for specimen collection. Findings included: a. According to laboratory personnel, during May 2021, the laboratory performed approximately 100,000 patient COVID-19 tests using a laboratory modified CareStart COVID-19 Antigen Rapid Diagnostic Test for passengers arriving at the Maui airport on behalf of the Maui Department of Health. Laboratory personnel stated that healthcare providers gave verbal self-collection instructions to patients, but were not involved in the collection of these patient sample swabs. The laboratory performed these COVID-19 tests on these patient self-collected samples. b.. The product insert for the unmodified CareStart COVID-19 Antigen Rapid Diagnostic Test stated: "Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril." Laboratory personnel stated that patients were instructed to self-collect swabs from only one nostril. c. On July 28, 2021, the date of the onsite survey, laboratory personnel were unable to provide a written protocol detailing the laboratory's procedure to as to how patient COVID-19 specimens are to be collected, how laboratory personnel/healthcare providers were to instruct patients for COVID-19 sample self-collection, and any written instructions for patients to follow for the laboratory's modified CareStart COVID-19 Antigen Diagnostic Test. d. See D5423.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to follow the laboratory's written procedure manual for all tests, assays, and examinations performed by the laboratory (see D5401), have available to laboratory personnel a written procedure for the laboratory's Cepheid GeneXpert HIV test (see D5401), establish performance specifications for the laboratory's modified CareStart COVID-19 Antigen Diagnostic Test (see D5423), perform Cepheid GeneXpert System maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer (see D5429), maintain an information or record system that included the identify of the personnel who performed the test or activity (see D5787), and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the analytic systems (see D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: 1. Based on a review of the laboratory's written protocols and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to follow the laboratory's written procedure manual for all tests, assays, and examinations performed by the laboratory. The findings include: a. The laboratory's "Assay Procedure Manual" stated: "All policies must be reviewed annually and documentation of review documented on each SOP [Standard Operating Procedure] policy signature page in this manual by the Laboratory Director," and "All testing personnel must review and understand objectives set by the procedure manual. Laboratory personnel must document review of the procedure manual by signing on each SOP policy signature page in this manual." b. For 4 (COVID/Influenza A & B /RSV, Chlamydia, Neisseria, and Trichomonas vaginalis) of 4 Cepheid GeneXpert procedures, the laboratory maintained no documentation to indicate that the laboratory director and testing personnel had reviewed these written protocols as required by the laboratory's "Assay Procedure Manual" policy stated above. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests: Influenza A and B, RSV, Chlamydia trachomatis, and Neisseria gonorrheae. 2. Based on a review of the laboratory's written protocols and interview with laboratory personnel on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to have available to laboratory personnel a written procedure for the laboratory's Cepheid GeneXpert HIV test. Findings included: a. It was the practice of the laboratory to perform patient HIV testing using the Cepheid GeneXpert instrument. b. A written HIV Cepheid GeneXpert protocol was not available for review on the day, July 28, 2021, of this onsite survey even though the laboratory reported on survey documents that it performs 730 patient HIV tests annually. c. Laboratory personnel stated that the laboratory began patient testing using the

	Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 61 HIV patient tests per month.
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 COVID-19 record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to establish performance specifications for the CareStart COVID-19 Antigen Rapid Diagnostic Test, which the laboratory modified. The findings include: a. It was the practice of the laboratory to test patient COVID-19 samples using a laboratory modified CareStart COVID-19 Antigen Rapid Diagnostic Test. Under the "Swab Sample Collection Procedure" detailed in the product insert for the unmodified CareStart COVID-19 Antigen Rapid Diagnostic Test, the manufacturer provides nasopharyngeal and anterior nasal swab collection protocols for use by trained healthcare providers. The manufacturer provided no instructions that would permit patients to self-collect nasopharyngeal and anterior nasal sample swabs. The laboratory modified the CareStart COVID-19 Antigen Rapid Diagnostic Test by testing samples that were self-collected by the patients, and not collected by trained healthcare providers. b. According to laboratory personnel, during May 2021, the laboratory performed approximately 100,000 patient COVID-19 tests using the laboratory modified CareStart COVID-19 Antigen Rapid Diagnostic Test for passengers arriving at the Maui airport on behalf of the Maui Department of Health. Laboratory personnel stated that healthcare providers gave verbal self-collection instructions to patients, but were not involved in the collection of these patient sample swabs. The laboratory performed these COVID-19 tests on these patient self-collected samples. c. In addition, the unmodified CareStart COVID-19 Antigen Rapid Diagnostic Test product insert stated: "Slowly roll the swab 5 times over the surface of the nostril. Using the same swab, repeat this collection process in the other nostril." Laboratory personnel stated that patients were instructed to self-collect swabs from only one nostril. d. On July 28, 2021, the date of the onsite survey, laboratory personnel were unable to provide a written protocol detailing the laboratory's procedure to as to how patient COVID-19 specimens are to be collected, how laboratory personnel/healthcare providers were to instruct patients for COVID-19 sample self-collection, and any written instructions for patients to follow for the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test. e. On July 28, 2021, the date of this onsite survey, laboratory personnel were unable to provide any documentation to indicate that, prior to testing patient COVID-19 self-collected samples, the laboratory had

	establishment of test performance specifications that included accuracy, precision, analytical sensitivity, and analytical specificity for its modified CareStart COVID-19 Antigen Rapid Diagnostic Test.
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 Cepheid GeneXpert System maintenance logs record review and laboratory personnel interview on July 28, 2021 at 09:30 a.m., it was determined that the laboratory failed to perform Cepheid GeneXpert System maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: a. It was the practice of the laboratory to perform patient COVID-19, Influenza A & B, RSV, Chlamydia, Neisseria, and HIV testing using the Cepheid GeneXpert instrument. b. The laboratory maintained no documentation to indicate that the following Cepheid GeneXpert instrument manufacturer required monthly maintenance had been performed in April 2021 and May 2021: archive tests, purge tests, and replace fan filters. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests using the Cepheid GeneXpert instrument: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on laboratory record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to maintain an information or record system that included the identity of the personnel who performed the test or activity. The findings include: a. Laboratory quality control records for patient tests performed using the Cepheid GeneXpert instrument failed to indicate the identity of laboratory personnel that performed and reviewed the quality control activity. b. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests using the Cepheid GeneXpert instrument: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.

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 quality assessment record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated correct problems identified in the analytic systems. The findings include: a. The laboratory's "Quality Assessment Plan of Doctors of Waikiki" stated: "QA [quality assessment] investigations, data compilation and documentation of all quality assessment activities will be the responsibility of the laboratory staff with appropriate reporting to the Laboratory Director or Technical Consultant." In addition, this written protocol stated that quality assessment activities would be documented using the following quality assessment forms: Calendar Checklist, Monthly Checklist-Analytic, Proficiency Testing Checklist, Test Tracking/Result Reporting/Chart Audit Form, LIS and EMR Accuracy and Result Storage Assessment, Review of Patient Population Reference Ranges, General Review Form, and Unexpected Event. b. On July 28, 2021, the date of the onsite survey, the laboratory maintained no documentation to indicate that the quality assessment forms detail above had been completed. c. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory reported performing an average of 304 patient COVID-19 tests per month and 61 patient tests each month of each of the following assays using the Cepheid GeneXpert instrument: Influenza A & B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratory Director, Moderate Complexity Testing, was not met. The laboratory director, moderate complexity testing, failed to possess a current Hawaii State Laboratory Director License issued by the State of Hawaii (see D6003), ensure that the laboratory's Cepheid GeneXpert COVID-19 test had the capability of providing the quality of results required for patient care (see D6012), ensure that the laboratory was enrolled in an HHS approved proficiency testing program for tests performed using the Cepheid GeneXpert test system (see D6015), ensure that quality assessments programs were followed (see D6021), ensure that the laboratory's Cepheid GeneXpert System was functioning properly (see D6025), ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results (see D6029), have available an approved written procedure

	manual for all tests, assays, and examinations performed by the laboratory (see D6031), and specify, in writing, the responsibilities and duties of each person engaged in testing using the Cepheid GeneXpert instrument (see D6032).
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of

	the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on personnel record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory director, moderate complexity testing, did not possess a current Hawaii State Laboratory Laboratory Director License issued by the State of Hawaii, where such licensing is required. Laboratory personnel confirmed that a State of Hawaii Laboratory Director License Application had not been submitted for the laboratory director.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) 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) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: Based on laboratory written protocols record review and laboratory personnel interviews on July 28, 2021 at 10:00 am, the laboratory director, moderate complexity testing, failed to ensure that the laboratory's Cepheid GeneXpert COVID-19 test had the capability of providing the quality of results required for patient care. See D5217.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on proficiency testing record review and laboratory personnel interviews on July 29, 2021 at 10:00 a.m., it was determined that the laboratory director, moderate complexity testing, failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for testing performed using the Cepheid GeneXpert test system. See D2000.
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 quality assessment record review and laboratory personnel interview on July 28, 2021 at 10:00 am, it was determined that the laboratory director, moderate complexity testing, failed to ensure that quality assessments programs were followed. See D5791.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on Cepheid GeneXpert System maintenance logs record review and laboratory personnel interview on July 28, 2021 at 09:30 am, it was determined that the laboratory director, moderate complexity testing, failed to ensure that the laboratory's Cepheid GeneXpert System was functioning properly. See D5429.
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 laboratory written protocol record review and laboratory personnel interviews on July 28, 2021 at 10:00 am, it was determined that the laboratory director, moderate complexity testing, failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. See D5209.
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 laboratory written protocol record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory director, moderate complexity testing, failed to have available an approved written procedure manual for all tests, assays, and examinations performed by the laboratory. See D5401.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on laboratory documents record review and laboratory personnel interview July 28, 2021 at 10:30 am, it was determined that the laboratory director, moderate complexity testing, failed to specify, in writing, the responsibilities and duties of each person engaged in the pre-analytic, analytic, and post analytic phases of Cepheid GeneXpert testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. Laboratory personnel stated that the laboratory began patient testing using the Cepheid GeneXpert instrument in April 2021. The laboratory performed an average of 304 patient COVID-19 tests per month and an average of 61 patient tests per month of each of the following tests using the Cepheid GeneXpert instrument: Influenza A and B, RSV, Chlamydia trachomatis, Neisseria gonorrheae, and HIV.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratory Director, High Complexity Testing, was not met. The laboratory director, high complexity testing, failed to possess a current Hawaii State Laboratory Director License issued by the State of Hawaii (see D6078), ensure that the laboratory's modified COVID-19 test had the capability of providing the quality of results required for patient care (see D6085), ensure the establishment of acceptable levels of analytical performance for the laboratory's patient COVID-19 test system utilizing the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test (see D6095), ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results (see D6102), ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process (see D6106), and specify, in writing, the responsibilities and duties of each person engaged in the pre-analytic, analytic, and post analytic phases of the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test (see D6107).

D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on personnel record review and laboratory personnel interview on July 28, 2021 at 10:00 a.m., it was determined that the laboratory director, high complexity testing, did not possess a current Hawaii State Laboratory Laboratory Director License issued by the State of Hawaii, where such licensing is required. Laboratory personnel confirmed that a State of Hawaii Laboratory Director License Application had not been submitted for the laboratory director.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on laboratory written protocols record review and laboratory personnel

	interviews on July 28, 2021 at 10:00 am, the laboratory director, high complexity testing, failed to ensure that the laboratory's modified COVID-19 test had the capability of providing the quality of results required for patient care. See D5217.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 the laboratory's COVID-19 test system record review and laboratory personnel interviews on July 28, 2021 at 10:00 a.m., it was determined that the laboratory director, high complexity testing, failed to ensure the establishment of acceptable levels of analytical performance for the laboratory's patient COVID-19 test system utilizing the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test. Findings included: For its patient COVID-19 testing, the laboratory used a modified CareStart COVID-19 Antigen Rapid Diagnostic Test, and failed to establish test performance specifications prior to reporting patient COVID-19 test results. See D5423.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 laboratory written protocol record review and laboratory personnel interviews on July 28, 2021 at 10:00 am, it was determined that the laboratory director, high complexity testing, failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. See D5209.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 laboratory written protocol record review and laboratory personnel interview July 28, 2021 at 10:00 am, it was determined that the laboratory director, high complexity testing, failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings included: The laboratory failed to establish written policies and procedures for the

	laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test for specimen collection. See D5311.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on laboratory documents record review and laboratory personnel interview July 28, 2021 at 10:30 am, it was determined that the laboratory director, high complexity testing, failed to specify, in writing, the responsibilities and duties of each person engaged in the pre-analytic, analytic, and post analytic phases of the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. According to laboratory personnel, during May 2021, the laboratory performed approximately 100,000 patient COVID-19 tests using the laboratory's modified CareStart COVID-19 Antigen Rapid Diagnostic Test for passengers arriving at the Maui airport on behalf of the Maui Department of Health.