

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0619870	(X3) Date Survey Completed 02/15/2022
Name of Provider or Supplier Waianae Coast Comp Health Ctr	Street Address, City, State 86-260 Farrington Hwy, Waianae, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory personnel competency records and confirmation by the Administrative Laboratory Director and General Supervisor #2 on 02/15/2022 at 11:30 a.m., it was determined that the laboratory failed to establish written policies and procedures to assess the competency of its 11 testing personnel. The findings include: 1. The Administrative Laboratory Director confirmed that the laboratory did not have a policy or procedure to describe testing personnel training, competency assessments and remediation activities. Testing personnel performed 5486 microbiology tests, 3101 general immunology tests, 192,157 chemistry tests and 51,317 hematology tests in 2021. 2. The Administrative Laboratory Director and General Supervisor #2 stated that they were available to perform testing on an on-call basis. The Administrative Laboratory Director stated that he came in over the previous weekend to perform a wet prep, an iRis urinalysis and a Liat COVID PCR test. Competency assessments for 2019, 2020 and 2021 were not performed for the Administrative Laboratory Director and General Supervisor #2.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on a review of laboratory procedure manuals and confirmation by the Administrative Laboratory Director on 02/15/2022 at 12:20 p.m., it was determined that the laboratory failed to establish written policies and procedures for an on going mechanism to monitor, assess, and when indicated, correct problems identified in its general laboratory systems. The findings include: 1. The Administrative Laboratory Director confirmed that the laboratory did not make available to its testing personnel written polices and procedures to assess the following: a. Patient confidentiality b. Complaint investigations c. Communications d. Personnel competency e. Proficiency testing performance

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 a review of laboratory procedure manuals and confirmation by the Administrative Laboratory Director on 02/15/2021 at 11:45 a.m., it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. The findings include: 1. The Administrative Laboratory Director confirmed that the laboratory did not have a written quality assessment plan that describes the ongoing review process of its practices related to test requests, specimen submission, handling and rejection, the identification and resolution of problems, and continuous improvement activities. 2. The Administrative Laboratory Director confirmed that testing personnel were not made aware of and were not involved in laboratory quality assessment activities.

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 a review of laboratory procedure manuals, quality control and instrument maintenance records and confirmation by the Administrative Laboratory Director on 02/15/2021 at 11:20 a.m. and the General Supervisor #2 on 02/15/2021 at 12:15 p.m., it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings include: 1. The Administrative Laboratory Director confirmed that the laboratory did not have a written policy or procedures that describes how the following analytic systems are assessed: a. Test procedures b. Accuracy and reliability of test systems, equipment,

instruments, reagents, materials, and supplies c. Specimen and reagent storage conditions d. Equipment/instrument/test system maintenance and function checks e. Method performance specifications f. Calibration and calibration verification activities g. Quality control results h. Corrective actions i. Test records 2. The General Supervisor #2 confirmed that monthly Beckman Coulter DXH800 hematology controls and Beckman Coulter DXC chemistry control records were not reviewed by the Laboratory Director. The Administrative Laboratory Director confirmed that laboratory information system chemistry control Levey Jennings charts and the hematology department Levey Jennings control charts were not reviewed by the Laboratory Director for failures, shifts and trends. 3. The General Supervisor #2 confirmed that monthly Beckman Coulter hematology and chemistry equipment maintenance logs were not reviewed by the Laboratory Director. 4. The laboratory performed 5486 microbiology tests, 3101 general immunology tests, 192,157 chemistry tests and 51,317 hematology tests in 2021.

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 procedure manuals and an interview with the Administrative Laboratory Director on 02/15/2022 at 12:30 p.m., it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the post analytic systems. The findings include: 1. The Administrative Laboratory Director confirmed that the laboratory did not have a written policy or procedures that describes how it assesses the following post analytic systems: a. Accuracy and completeness of laboratory test reports to include patient information, test results, normal ranges and disposition of unacceptable specimens b. Laboratory test turn-around times c. Notification and communication of critical value results d. Notification and communication of COVID 19 test results per the Cares Act e. Periodic accuracy of results sent from interfaced systems 2. The laboratory performed 5486 microbiology tests, 3101 general immunology tests, 192,157 chemistry tests and 51,317 hematology tests in 2021.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a review of laboratory procedures and confirmation by the Administrative Laboratory Director on 02/15/2022 at 12:30 p.m., it was determined that the laboratory failed to establish written procedures that described the duties of the Technical Supervisor and Clinical Consultant to include the delegation of Laboratory Director responsibilities to each of the three General Supervisors. The findings include: 1. General Supervisor #2 confirmed on 02/15/2022 at 12:35 p.m. that the review of monthly laboratory quality control and equipment maintenance logs were not reviewed by the Laboratory Director. These responsibilities were not delegated to a General Supervisor. 2. General Supervisor #2 confirmed on 02/15/2022 at 12:35 p.m. that the responsibility of performing annual competencies on testing personnel and general supervisors was not delegated to a General Supervisor. General Supervisor #2 and General Supervisor #3 performed annual competency assessments on each other.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review of laboratory procedure manuals, records and confirmation by the Administrative Laboratory Director on 02/15/2021 at 1:00 p.m., it was determined that the Laboratory Director failed to ensure that a quality assessment program was established for the chemistry, hematology, general immunology and microbiology testing it performed. The findings include: 1. The Laboratory Director did not make available to its testing personnel written policies and procedures to monitor, assess and correct problems identified in its general laboratory systems. See CFR 493.1239, D tag D5291. 2. The Laboratory Director did not have a written quality assessment plan that describes the ongoing review process of its practices related to its preanalytic systems. See CFR 493.1249, D tag D5391. 3. The Laboratory Director did not have a written policy or procedures that describes the ongoing review process of its practices related to its analytic systems. See CFR 493.1289, D tag D5791. 4. The Laboratory Director did not have a written policy or procedures that describes how it assesses its post analytic systems. See CFR 493.1299, D tag D5891.

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 a review of records and confirmation by the Administrative Laboratory Director on 02/15/2021 at 12:35 p.m., it was determined that the Laboratory Director

did not ensure that policies and procedures were established for monitoring testing personnel who conduct preanalytical, analytical, and post analytical phases of testing. Findings include: 1. The Administrative Laboratory Director stated that the laboratory did not have a policy or procedure to describe testing personnel training, competency assessments and remediation activities. See CFR 493.1235, D tag D5209. 2. Testing personnel performed 5486 microbiology tests, 3101 general immunology tests, 192,157 chemistry tests and 51,317 hematology tests in 2021.

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 a review of laboratory procedures and confirmation by the Administrative Laboratory Director on 02/15/2022 at 12:30 p.m., it was determined that the Laboratory Director failed to specify in writing, the responsibilities and duties of each consultant, the Administrative Laboratory Director, each of the 3 general supervisors, as well as each of the 11 testing personnel engaged in the performance of the preanalytic, analytic, and post analytic phases of testing, that identifies which examination and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisor or director review is required prior to reporting patient test results.

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high 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 testing personnel records and confirmation by the Administrative Laboratory Director on 02/15/2022 at 11:35 p.m., it was determined that the laboratory failed to have current state of Hawaii license documentation for 2 of 11 testing personnel. The findings include: 1. Each testing personnel must possess a current state of Hawaii medical technologist license to perform nonwaived tasting. Laboratory testing personnel licenses are scanned into the laboratory information system. The Administrative Laboratory Director confirmed that licenses for testing personnel #1 and #9 were not scanned into the system.