Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0619870	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Waianae Coast Comp Health Ctr	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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and laboratory personnel interviews conducted on 7/9/19 , the laboratory failed to maintain copies of all 2018 PT records, including a copy of the PT report forms used by the laboratory to record PT results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. Findings included: a. For 2018, the laboratory was enrolled in the following PT modules: Alcohol, Blood Gases, Cardiac Marker/Isoenzymes, Chemistry (Basic & Comprehensive), Glycohemoglobin, Lipids, Therapeutic Drug Monitoring, Urine Drug Screening, Coagulation, Blood Cell Identification, Hematology with WBC Differential, D-dimer, Throat/Urine Culture, Clinical Microscopy, and Urinalysis. b. The laboratory maintained no copies of the laboratory's 2018 PT reports forms used by the laboratory to record PT results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director. c. Laboratory personnel confirmed that copies of the 2018 PT attestation statements not maintained by the laboratory.

D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on bacteriology media quality control record review and laboratory personnel interviews conducted on 7/9/19, the laboratory failed to maintain documentation to indicate that, before or concurrent with initial use, the laboratory checked each batch of media for its ability to support growth for batches of Remel blood agar media received during 2018. Findings include: a. In 2018, it was the practice of the laboratory to test patient Strep Screen samples using Remel blood agar media. b. The laboratory maintained no documentation to indicate that, before or concurrent with initial use, the laboratory checked each batch of Remel blood agar media for its ability to support growth received and used for patient Strep Screen testing in 2018. c. According to laboratory records, the laboratory performed and reported approximately 3,000 patient Strep Screen culture results in 2018. d. Laboratory personnel confirmed that in 2018 each batch of Remel blood agar media received and used was not checked for its ability to support growth before or concurrent with initial use.
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 procedure manual record review and laboratory personnel interviews conducted on 7/9/19, 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, including a written protocol that detailed the laboratory's system that, twice a year, evaluated and defined the relationship between tests results when the same test is performed using different methodologies or instruments as required by 42 C.F.R. 493.1281(a). Findings included: a. It was the practice of the laboratory to perform patient troponin testing on either of two Siemens Stratus CS instruments. b. Although the laboratory maintained documentation to indicate that the laboratory had evaluated and defined the relationship between troponin test results for two instruments twice a year, the laboratory maintained no written protocol detailing the procedure used. c. Laboratory personnel confirmed that no such written protocol was available. d. According to laboratory records, the laboratory performed 3,147 troponin tests from 7/1/18-6/30/19.