Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0646259	12/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hawaii Dept Of Health	2725 Waimano Home Rd, Pearl City, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Chemical Response Section (CRS) test method verification record review on December 10, 2019, the laboratory failed to document all test method verification activities. Findings included: a. In the laboratory's CRS, the laboratory was prepared to perform patient tests related to chemical terrorism using instruments manufactured by Agilent Technologies. At least twice annually, the laboratory's CRS verified the accuracy of the patient tests offered by participating in the Centers for Disease Control and Prevention (CDC) required proficiency testing. b. For 2019, although CRS participated satisfactorily in CDC's required proficiency testing, the laboratory maintained no documentation that proficiency testing result reports were appropriately reviewed by laboratory personnel. c. Documentation of such reviews were required by the laboratory's protocol.
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 laboratory personnel interviews and Chemical Response Section (CRS) instrument maintenance record review on December 10, 2019, the laboratory failed to establish a written maintenance protocol that ensures instrument performance that is necessary for accurate and reliable test results and test result reporting. Findings included: a. In the laboratory's CRS, the laboratory was prepared to perform patient tests related to chemical terrorism using instruments manufactured by Agilent Technologies. b. Although the laboratory documented maintenance performed on the Agilent Technologies instruments, the laboratory maintained no written protocols detailing any laboratory required maintenance procedures and the frequency such maintenance must be performed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and bacteriology media quality control record review on December 11, 2019, the laboratory failed to document all bacteriology media quality control procedures performed. Findings included: a. In the microbiology section, the laboratory was performed and reported approximately 29,000 patient test results annually. b. For 1 (accession number 19K012) of 1 randomly selected patient bacteriology specimen received by the laboratory on October 7, 2019, the laboratory maintained no documentation of the following: 1. The lot numbers of the ATCC organisms used by the laboratory to check each batch of media used to culture this patient's specimen for the media's ability to support growth and, as appropriate, select or inhibit specific organism or produce a biochemical response; and, 2. The lot numbers of the commercially and/or in-house manufactured media used to culture this patient's specimen. c. For 1 (accession number 1900013102) of 1 randomly selected patient Neisseria gonorrhoeae (GC) specimen received by the laboratory on October 28, 2019, the laboratory maintained no documentation of the following: 1. The lot numbers of the ATCC organisms used by the laboratory to check each batch of media used to culture this patient's specimen for the media's ability to support growth; and, 2. The lot numbers of the commercially manufactured media used to culture this patient's specimen. d. According to laboratory personnel, it was not the practice of the laboratory to document the lot numbers of the ATCC organisms used to check each batch of media, and it was not the practice of the laboratory to document the lot numbers of the commercially and/or in-house manufactured media used to culture each patient specimen.
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 laboratory personnel interviews and bacteriology quality assessment record review on December 11, 2019, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor and assess bacteriology analytic systems. Findings included: a. In the microbiology section, the laboratory was performed and reported approximately 29,000 patient test results annually. b. For CO2 incubator VWR51014995, laboratory records indicated that quality assessment reviews of the temperature charts was required by the laboratory bimonthly basis. c. The laboratory maintained no documentation of the bimonthly required CO2 incubator VWR510149951 quality assessment temperature chart reviews for the March/April 2019, July/August 2019, and September/October 2019 charts.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 laboratory personnel interviews and bacteriology media quality control record review on December 11, 2019, individuals performing high complexity bacteriology testing failed to adhere to the laboratory's media quality control polices. Findings included: a. In the microbiology section, the laboratory was performed and reported approximately 29,000 patient test results annually. b. For 1 (accession number 19K012) of 1 randomly selected patient bacteriology specimen received by the laboratory on October 7, 2019, the laboratory's media quality control documentation indicated: 1. For the lot (#844989, expiration date November 6, 2019) MacConkey agar plate used to culture this patient's specimen, laboratory documentation indicated that Salmonella typhimurium ATCC 14096 was used to check the media's ability to support growth. However, the laboratory's written protocol required the use of Salmonella typhimurium ATCC 14028. 2. For the lot (#844989, expiration date November 6, 2019) MacConkey agar plate used to culture this patient's specimen, laboratory documentation indicated that Shigella flexneri ATCC 12022 was used to check the media's ability to support growth. However, the laboratory's written protocol required the use of Shigella flexneri ATCC 14022. 3. For the lot (#7082926, expiration date February 28, 2022) Lysine Iron agar plate used to culture this patient's specimen, laboratory documentation indicated that Salmonella typhimurium ATCC 14096 was used to check the media's ability to support growth. However, the laboratory's written protocol required the use of Salmonella typhimurium ATCC 14028. 4. For the lot (#7082926, expiration date February 28, 2022) Lysine Iron agar plate used to culture this patient's specimen, laboratory documentation indicated that Shigella flexneri ATCC 12022 was used to check the media's ability to support growth. However, the laboratory's written protocol required the use of Shigella flexneri ATCC 14022.