Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0695909	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
State Of Hawaii Department Of Health Std Clinic	3627 Kilauea Ave Rm 305, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency records, the CMS Casper record and interview with the laboratory Director and the laboratory Technical Supervisor on July 12, 2018, the laboratory failed to attain an overall testing event score of at least 80 percent resulting in unsatisfactory performance for Bacteriology CAP D5-A event 1 of 2018. Findings include: a. For CAP D5-A 2018 gram Stain identification, and Morphology: the laboratory failed 2 out of 5 slide reviews, achieving an overall event score of 60%. Results: Gram stain: D5-01, Acceptable D5-02, Acceptable D5-03 - Unacceptable D5-04 - Unacceptable D5-05, Acceptable Morphology: D5-01, Acceptable D5-02- Unacceptable D5-03- Unacceptable D5-04, Acceptable D5-05, Acceptable b. The laboratory Director and Technical supervisor confirmed this deficient score by interview on July 12, 2018 at approximately 10:00 am. c. The laboratory reports performing approximately 3000 Gram stains annually and 750 Morphology reviews annually.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a random review of patient records on July 12, 2018, the laboratory failed to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. Findings Include: a. Upon random selection of patient record review, one of eight patients selected did not have the correct date of birth transcribed from the initial patient file jacket to the patients electronic report records. b. The patients date of birth as indicated on the file jacket was 12/22/1991 and was manually transcribed into the patients electronic medical record as 12-27-1991 on July 11, 2017 at 11:15 am. c. The manual transcription error was verified and confirmed by the Technical supervisor by interview on July 12, 2018 at approximately 11:00 pm. d. The laboratory reports performing approximately 4500 patient specimens annually.
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 reapportions 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: The laboratory director to ensure 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. Findings Include: a. The laboratory failed to achieve satisfactory Proficiency Testing scores for event 1, 2018 of at least 80%. See D tag 2020 b. The laboratory director failed to ensure that patient test reports and records are performed accurately. See D tag 5801 c. The laboratory reports performing 4,500 patient specimens annually.