

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0695909	(X3) Date Survey Completed 03/25/2021
Name of Provider or Supplier State Of Hawaii Department Of Health Std Clinic	Street Address, City, State 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory personnel email communications and Gram stain quality control record review on March 24, 2021, the laboratory failed to establish over time statistical parameters for unassayed Gram stain quality control slides through concurrent testing of quality control materials having previously determined statistical parameters. Findings included: a. It was the practice of the laboratory to perform Gram stain quality control procedures using unassayed Gram positive and negative quality control slides made by another laboratory to monitor its patient testing. b. Upon receipt of the unassayed Gram stain quality control slides, the laboratory did not test the newly received unassayed quality control slides concurrent with previously established quality control slides before using the newly received unassayed quality control slides to independently monitor patient Gram stain testing. c. On March 2, 2020, the laboratory tested and reported one patient Gram stain result in which Gram stain quality procedures were performed. However, the laboratory maintained no</p>

documentation to indicate that statistical parameters for the unassayed Gram stain quality control slides that were used on March 2, 2020 had been established over time by the laboratory through concurrent testing with quality control slides having previously determined statistical parameters.