Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0695909	03/10/2026
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
D0000	A recertification survey was conducted March 10, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer instructions, laboratory policies, temperature/humidity records, and interview with the Technical Supervisor (TS), the laboratory failed to define, monitor, and document room temperature and/or humidity ranges consistent with manufacturer instructions for 231 of 231 laboratory tubes, collection kits, and instruments. Findings Included: 1) During a tour of the laboratory on 3/10/2026 at 11:23 AM, the following items were directly observed stored and in use: a. 30 Red Top Becton Dickinson (BD) Vacutainer Tubes, Lot Number 5036669, Manufacturer storage temperature requirements - 4 to 25 degrees Celsius b. 50 Gold Top BD Vacutainer Tubes, Lot Number 5121585, Manufacturer storage temperature requirements - 4 to 25 degrees Celsius c. 50 Aptima Unisex Swab Specimen Collection Kits for Endocervical and Male Urethral Swab, Manufacturer storage temperature requirements - 15 to 30 degrees Celsius d. 50 Aptima Multitest Swab Specimen Collection Kits, Lot Number 918848, Manufacturer storage temperature

	requirements - 15 to 30 degrees Celsius e. 1 Olympus CH30RD 100 Microscope, Serial Number T39H14616, Manufacturer humidity requirements (Olympus Instructions CH30/CH40 Biological Microscope) - 80% for temperatures up to 31 degrees Celsius, decreasing linearly through 70% at 34 degrees Celsius, 60% 37 degrees Celsius, to 50% relative humidity at 40 degrees Celsius. 2) Review of the laboratory's policies did not define room temperatures. 3) Review of the laboratory's temperature records titled 'State of Hawaii Department of Harm Reduction Services Branch STI Clinic Laboratory Room Temperature Log revealed an acceptable room temperature range of 2 to 30 degrees Celsius, and no monitoring or documentation of humidity. 4) In an interview on 3/10/2026 at 11:30 AM in the laboratory, the TS confirmed the laboratory did not define acceptable room temperature ranges in accordance with manufacturer instructions, and did not monitor and document humidity.
D5801	TEST REPORT CFR(s): 493.1291(a) (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 review of the laboratory's policies and procedures, patient test records, QA reviews, and interview with the Technical Supervisor, the laboratory failed to ensure test results and other patient-specific data were accurately and reliably reported at point of data entry for one of five patients reviewed (Random review from January 2025 to December 2025). Findings Included: 1) Review of the laboratory's policy titled 'Quality Assurance/Control Program Review' stated the following: "Laboratory Director Designee conducts annual review of clinicians' collection, processing (including Gram staining), and interpreting of specimens. This includes timeliness in assessing NaCL vaginal wet prep for T. vaginalis Two visits from the State Laboratory Director to assess laboratory quality assurance/control activities Quarterly chart review: comparison of 10 patients with stat lab Gram-stained specimens... Discrepant Analysis of Gram stained specimen with lab results. See QA Procedures binder. In depth Quality Assurance procedures are documented in QA binder kept in clinic manager's office... Quality control on KOH reagent is completed each day on which a vaginal wet prep examination is done. Positive control is visualizing lysed vaginal epithelial cells' negative control (NaCl) is visualizing intact vaginal epithelial cells. This is documented in the stat lab book and reviewed by the Laboratory Director designee on a monthly basis..." 2) Review of a random sampling of five patient test report workups in 2025, and the laboratory's test record logbook, revealed the following inconsistency in reporting: Test Report Workup: Date: 2/3/2025, Patient ID No. - 121312, Result: Whiff Test (positive), Clue cells (nothing reported), NaCl (negative), KOH (negative), WBC (10-100/OIM). Laboratory's logbook of test records: Date: 2/3/2025, Patient ID No. - 121312, Result: Clue cells (Positive), KOH (negative). 3) Review of the laboratory's QA reviews lacked documentation of this incident and contained no evidence of corrective action to address the inaccurate data

	entry identified on 2/3/2025. 4) In an interview on 3/10/2026 at 10:11 AM in the laboratory, the TS confirmed he did not identify this incident and correct the discrepancy.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with the Technical Supervisor (TS), the laboratory director (LD) failed to approve a procedure manual for online test result reporting of Sexually Transmitted Infection (STI) tests via Aveva software for two of two years (2024 and 2025). Findings Included: 1) Review of the laboratory's policy titled "State of Hawaii Department of Health, Harm Reduction Services Branch Communicable Disease and Public Health Nursing Division, STI/HIV Clinic, Provision of Online Results of STI Tests via Aveva" revealed no review, approval dates and signature by the LD. 2) In an interview on 3/10 /2026 at 10:40 AM in the laboratory, the TS confirmed the laboratory reported out results telephonically and using the online Aveva software system, but the Standard Operating Procedures (SOP) had not yet been reviewed and approved by the LD.