

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 12D0695909	(X3) Date Survey Completed 12/06/2024
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
D0000	A recertification on-site survey was conducted on 12/6/2024, the laboratory was surveyed under 42 CFR Part 493 CLIA regulations and was found to have a standard level deficiency cited.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with Technical Consultant #1, the laboratory failed to ensure cotton swabs found in patient exam room did not exceed their expiration date for KOH and direct wet mount tests as evidenced by: 1. In direct observation on 12-06-2024 at 1045 in the patient exam room, the following reagents were found to be expired: 23-sterile cotton tip application utility lot 5842 expiration date 10-01-2023. 2. In interview with technical consultant #1 12-06-2024 at 1046 he acknowledged that the the cotton tips were expired and confirmed that they were using them for KOH and direct wet mount tests. 3. According to the CMS-116, the laboratory performs 2080 KOH and direct wet mounts tests per year.</p>