

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0695909	<b>(X3) Date Survey Completed</b>  12/06/2022
<b>Name of Provider or Supplier</b>  State Of Hawaii Department Of Health Std Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and document review, the laboratory failed to label gram staining reagent in use to indicate expiration date. Findings include: a. During the virtual tour of the laboratory's gram staining area on 12/6/22, the surveyor observed that the working solution bottle of ethyl alcohol labeled, 'Ethyl Alcohol reagent, Denatured, Spectrograde, Contains 5% 2-PrOH and 5% MeOH,' was not labeled with an expiration date. b. Observation showed an amber ethyl alcohol stock solution bottle, labeled 'Ethyl Alcohol reagent, Denatured, Spectrograde, Contains 5% 2-PrOH and 5% MeOH,' from which the working solution was transferred. c. Interview at 1.15 p.m. (PST) on 12/6/22 with testing personnel (TP#1) confirmed that the contents of the ethyl alcohol working solution bottle were transferred from the stock solution, and that the ethyl alcohol working solution bottle was currently in use by the laboratory not labeled with an expiration date. d. Review of procedure, 'QC for Reagents,' revealed "expiration dates inclusive of month, day and year will be written on all working gram stain reagent and daily use reagent bottles, the bottles will be checked monthly for the expiration date documented on the 'Solutions expiration dates log' and the review documented on the log." e. The technical consultant #2 and QA/ Training Coordinator confirmed on 12/6/22 at 4.35 p.m. (PST) that the ethyl alcohol working solution bottle was not labeled with an expiration date. f. The laboratory performs an annual test volume of 1070, of which 800 are gram stains.</p>

**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 observation, interview and document review, the laboratory failed to ensure preventive maintenance (PM) service was performed on two of two microscopes. Findings include: 1. Based on observation, maintenance service tags, dated 10/21/21 were affixed to microscopes, Zeiss S/N: 123655 (#1) and Olympus S/N: 9H14616 (#2). 2. Interview at 3.24 p.m. (PST) on 12/6/22 with testing personnel (TP#1) revealed that microscope (#1) is the primary one in use and microscope (#2) is used as a backup. TP#1 confirmed at 3.24 p.m. (PST) that per the date on the affixed service tags both microscopes were past due for preventive maintenance service. 3. Review of procedure, 'Equipment Maintenance,' showed that microscopes will be serviced annually and the most recent service date recorded on the microscope base. 4. Review of maintenance documentation dated on 10/21//21, showed that annual preventive maintenance service had been performed on both microscopes in 2021. The laboratory had no record of completed annual service for 2022 at the time of the survey. 5. The technical consultant (TC#2) and QA/ Training Coordinator confirmed on 12/6/22 at 4.35 p.m. that the laboratory failed to perform and document preventive maintenance of the microscopes as defined by the laboratory's procedure. 6. The laboratory reports an annual test volume of 1070.