

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D2076582	<b>(X3) Date Survey Completed</b>  01/25/2023
<b>Name of Provider or Supplier</b>  Queen's Cancer Center Pob1	<b>Street Address, City, State</b>  1380 Lusitana St Suite 608, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory record review and an interview with the testing personnel and general supervisor on 01/25/2023 at 2:00 PM, it was determined that the laboratory failed to follow its written policies and procedures to assess the competency of the individual performing routine chemistry and hematology testing in 2020. The laboratory performed an annual volume of 3100 Alfa Wasserman ACE Alera comprehensive metabolic profiles and 3600 Abbott CellDyn Emerald complete blood counts.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of ACE Alera Clinical Chemistry System Maintenance Logs and an interview with the testing personnel on 01/25/2023 at 2:30 PM, it was determined that the laboratory failed to perform and document maintenance as defined and with at least the frequency specified by the manufacturer Alfa Wasserman Diagnostic Technologies. The laboratory performed an annual volume of 3100 ACE Alera</p>

comprehensive metabolic profiles. The findings include: 1. Bi-Annual maintenance to include replace ISE Pump Tubing and inspect ISE electrodes was performed once in 2021 2. Annual maintenance to include replace all ISE tubing was not documented in 2021 3. Monthly maintenance to include rinse probe and fluid lines with 10% bleach, clean bottle caps and cap connectors, perform daily sample delay/optical calibration /table offset, and clean reference housing was not documented for 3 of 12 months (April, May, July) in 2022

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(6)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on a review of ACE Alera Clinical Chemistry System Maintenance Logs and an interview with the testing personnel on 01/25/2023 at 2:30 PM, it was determined that the laboratory director failed to ensure acceptable levels of its routine chemistry analytical performance on the Alfa Wasserman ACE Alera test system were maintained. See D5429.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on laboratory record review and an interview with the testing personnel and general supervisor on 01/25/2023 at 2:00 PM, it was determined that the laboratory director failed to ensure that laboratory policies and procedures for monitoring the individual conducting preanalytical, analytical and post analytical phases of routine chemistry and hematology testing were followed. See D5209.