

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 12D2040245	<b>(X3) Date Survey Completed</b> 01/27/2023
<b>Name of Provider or Supplier</b> Qmc Punchbowl Nuclear Medicine Department	<b>Street Address, City, State</b> 1301 Punchbowl St, 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 technical consultant on 01/27/2023 at 9:15 AM, it was determined that the laboratory failed to follow its written policies and procedures to assess the competency of one of five Daxor BVA-100 blood volume testing personnel in 2022. The laboratory performed an annual volume of 200 hematology analyses with this test system.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory record review and an interview with the testing personnel and technical consultant on 01/27/2023 at 9:30 AM, it was determined that the laboratory failed to at least twice annually verify the accuracy of the Daxor BVA-100 blood volume testing it performed in 2022. The laboratory performed an annual volume of 200 blood volume analyses.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on laboratory record review and an interview with the testing personnel and technical consultant on 01/27/2023 at 9:30 AM, it was determined that the laboratory director failed to ensure its quality assessment program was maintained for the Daxor BVA-100 blood volume testing services it provided. Biannual accuracy verification of this test system was performed once in 2022. See D5217.

**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 technical consultant on 01/27/2023 at 9:15 AM, it was determined that the laboratory director failed to ensure that laboratory policies and procedures for monitoring the individuals conducting preanalytical, analytical and post analytical phases of hematology analyses were followed. See D5209.