

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  12D0877885	<b>(X3) Date Survey Completed</b>  02/03/2025
<b>Name of Provider or Supplier</b>  Samuel Mahelona Memorial Hospital	<b>Street Address, City, State</b>  4800 Kawaihau Rd, Kapaa, 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: The surveyor's review of laboratory procedures and an interview with the emergency department (ED) manager and technical consultant on February 3, 2025 at 11:00 AM revealed the laboratory failed to establish and follow written policies and procedures to assess the competency of its technical consultant. The findings include: 1. Laboratory technical consultant services are provided to the hospital as part of a management agreement with another CLIA facility. 2. The 2023-2024 performance assessment on the technical consultant was performed by an individual not listed on the laboratory's Form CMS-209. This assessment was reviewed and approved by the Laboratory Director of the CLIA facility responsible for the management agreement.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: The surveyor's review of laboratory records and confirmation by the ED manager on 2/3/2025 at 11:00 AM revealed the laboratory director failed to ensure the laboratory's quality control program was maintained to ensure the quality of its Abbott iSTAT</p>

hematology and routine chemistry POCT services. The findings include: 1. Laboratory testing personnel failed to adhere to the laboratory's quality control procedure to perform annual correlation studies between iSTAT system clinical laboratories. See D tag D6072. 2. The laboratory Quality Assurance Plan-Point of Care Testing procedure Specific Objectives A. Responsibilities states the "execution of the POCT's quality management program rests with the CLIA laboratory director working with the ED manager to ensure that the program is consistently implemented through the POCT program". Specific Objectives B. Quality Assurance Aims 6. Personnel Competency states the Laboratory Director and ED manager "assures that personnel follows SOPs and systems function as planned".

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

(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:  
The surveyor's review of laboratory procedures and an interview with the ED manager and technical consultant on February 3, 2025 at 11:00 AM revealed the laboratory director failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure and maintain their competency. The findings include: 1. The laboratory Quality Assurance Plan-Point of Care Testing procedure Specific Objectives A. Responsibilities states the "Ultimate responsibility for development and execution of the POCT's quality management program rests with the CLIA laboratory director working with the ED manager to ensure that the program is consistently implemented through the POCT program". Specific Objectives B. Quality Assurance Aims 6. Personnel Competency is one of eight responsibilities listed. 2. The ED manager stated a nursing administrator performed the assessment of her ability to execute the POCT's quality management program. The nursing administrator is not listed on the laboratory's Form CMS-209. 3. The ED manager is listed as testing personnel #2 (TP2) on the laboratory's Form CMS-209. The ED manager stated a senior testing personnel performed her annual competency assessment.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
The surveyor's review of laboratory procedures and an interview with the emergency

department (ED) manager and technical consultant on February 3, 2025 at 11:00 AM revealed the laboratory director failed to specify in writing the responsibilities and duties of the technical consultant and 18 of 18 testing personnel performing Abbott iSTAT hematology and routine chemistry POCT. The findings include: 1. Laboratory technical consultant services are provided to the hospital as part of a management agreement with another CLIA facility. Written responsibilities and duties for this individual were not documented in the Quality Assurance Plan-Point of Care Testing procedure Specific Objectives A. Responsibilities. 2. iSTAT testing personnel authorized responsibilities and duties were not documented in the Quality Assurance Plan-Point of Care Testing procedure Specific Objectives A. Responsibilities. 3. The laboratory performed an annual volume of 2416 hematology and 8834 routine chemistry tests in 2024.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1425(b)(3)

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

This STANDARD is not met as evidenced by:  
The surveyor's review of laboratory procedures and records, and an interview with the ED manager and Technical Consultant on 2/3/2025 at 11:00 AM revealed testing personnel failed to adhere to the laboratory's quality control procedure SMMH.SOP. 06.335.0810.0, updated 12-2019. The procedure states "Correlation studies between the iSTAT system Clinical laboratories are performed yearly". The ED manager confirmed correlation studies were not performed in 2023 and 2024. The laboratory performed an annual volume of 2416 hematology and 8834 routine chemistry tests in 2024.