

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D0658271</p>	<p>(X3) Date Survey Completed</p> <p>03/27/2025</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Clinico Mayaguez</p>	<p>Street Address, City, State</p> <p>Urb Perez Morris, Calle Mayaguez 142, San Juan, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Mayaguez on March 27, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on March 27, 2025.</p>
<p>D5437</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration records, manufacturer's instructions reviewed and laboratory supervisor interview on March 27, 2025 at 12:17 PM, it was determined that the laboratory failed to perform the calibration procedures with at least the frequency recommended by the manufacturer's instructions (annually) for the hematology tests performed by the Sysmex XN-1000 hematology system. The laboratory process and report 1,488 out of 1,488 from January 2024 to December 2024. The findings include: 1. The laboratory uses a Sysmex XN-1000 hematology</p>

system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration procedures annually. 3. On March 27, 2025 at 12:07 PM, the calibration records of XN-1000 hematology system showed that the laboratory did not perform at least annually the calibration procedures that was included in the annually preventive maintenance. The last calibration procedures were done on July 2023. 4. The laboratory supervisor confirmed on March 27, 2025 at 12:17 PM, that the laboratory did not perform at least annually the calibration procedures for the XN-1000 hematology system. The laboratory processed and reported 1,488 CBC patient samples from from January 2024 to December 2024.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

(b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

This STANDARD is not met as evidenced by:
Based on Hematology quality control records review and interview with the laboratory supervisor on March 27, 2025 at 12:25 PM, it was determined that the laboratory supervisor failed to ensure that the quality control of hematology specialty were follow. Refer to D 5437.