

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658113	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier Laboratorio Clinico Roxel Inc	Street Address, City, State 104 East Font Martello Street, Humacao, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Roxel on April 10, 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 April 10, 2025.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration verification records, manufacturer's instructions, and laboratory director interview on April 10, 2025 at 11:03 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the</p>

frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the XN-550 hematology system. The findings include:

1. The laboratory uses a XN-550 hematology system for CBC (Complete blood count) patient's tests.
2. Review of the manufacturer's instructions on April 10, 2025 at 11:00 AM showed that the laboratory must perform the calibration verification procedures every six months.
3. On April 10, 2025 at 11:03 AM, the calibration verification records of XN-550 hematology system showed that the laboratory did not perform at least every 6 months the calibration verification procedures.
4. The laboratory processed and reported 1,246 CBC patient samples from January 1, 2024 to April 10, 2025.
5. The laboratory director confirmed on April 10, 2025 at 11:16 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the XN-550 hematology system.