

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2058614	(X3) Date Survey Completed 08/07/2025
Name of Provider or Supplier Laboratorio Clinico Plaza Caparra	Street Address, City, State Centro Comercial Plaza Caparra, Carretera 23, Guaynabo, 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 the Laboratorio Clinico Plaza Caparra on August 7, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on August 7, 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: A. Based on general chemistry calibration verification records review (years 2024-2025) and interview with the laboratory director on August 7, 2025, at 11:00 AM, it</p>

was determined that the laboratory did not perform the Vitamin B12 calibration verification procedure at least once every six months. The laboratory processed and reported 869 out of 2,691 Vitamin B12 patient tests from January 1, 2024, to August 6, 2025, without performing the required calibration verification. The findings include: 1. The laboratory used Roche Diagnostics Cobas e 411 Analyzer to perform Vitamin B12 testing. (Reviewed on August 7, 2025 at 11:00 AM) 2. Review of general chemistry calibration verification records showed that the laboratory failed to perform Vitamin B12 calibration verification procedure in the years 2024 and 2025. 3. The laboratory processed and reported 869 out of 2,691 Vitamin B12 patient testing from January 1, 2024, to August 6, 2025, without calibration verification. 4. On August 7, 2025, at 11:30 AM, the laboratory director confirmed that the laboratory did not perform Vitamin B12 the calibration verification procedure at least once every six months. B. Based on endocrinology calibration verification records review (years 2024-2025) and interview with the laboratory director on August 7, 2025, at 11:00 AM, it was determined that the laboratory did not perform the 25-hydroxyvitamin D (25-OH-D) calibration verification procedure at least once every six months. The laboratory processed and reported 1,354 out of 4,768 25-OH-D patient tests from January 1, 2024, to August 6, 2025, without performing the required calibration verification. The findings include: 1. The laboratory used the Roche Cobas e411 Analyzer to perform 25-OH-D testing. (Reviewed on August 7, 2025 at 11:00 AM) 2. Review of endocrinology calibration verification records showed that the laboratory failed to perform 25-OH-D calibration verification procedure in the years 2024 and 2025. 3. The laboratory processed and reported 1,354 out of 4,768, 25-OH-D patient testing from January 1, 2024, to August 6, 2025, without calibration verification. 4. On August 7, 2025, at 11:30 AM, the laboratory director confirmed that the laboratory did not perform 25-OH-D the calibration verification procedure at least once every six months.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(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;

This STANDARD is not met as evidenced by:
Based on general chemistry and endocrinology quality control records review (years 2024-2025) and interview with the laboratory director on August 7, 2025, at 11:30 AM, it was determined that the laboratory director failed to fulfill her responsibility to ensure at least once every six months, the calibration verification procedures for the Vitamin B12 and 25-OH-D assay. Refer to D5439.