

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669529	(X3) Date Survey Completed 09/10/2025
Name of Provider or Supplier Laboratorio Clinico Martin	Street Address, City, State Calle F , Num 121, Esq Ave Betances,, Bayamon, 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 Martin on September 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 September 10, 2025.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2024-2025) and laboratory testing personnel interview on September 10, 2025 at 11:40 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials (normal and abnormal controls), when the laboratory processed and reported 368 patient urinalysis samples from June 2, 2025 to September 10, 2025. The findings include: 1. The laboratory performs urinalysis tests with the Mission U120 Ultra Urine Analyzer. 2. The urinalysis quality control records reviewed (years 2024-2025) on September 10, 2025 at 11:40 AM, showed that from June 2, 2025 to September 10, 2025, there was no evaluation of the manufacturer's stated values for the normal</p>

	<p>control material lot number UB1526051A, and abnormal control material lot number UB1526052B, prior to placing them in routine use on June 2, 2025. 3. The laboratory testing personnel confirmed on September 10, 2025 at 11:45 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests prior to placing them in routine use, performed by the Mission U120 Ultra Urine Analyzer, when they processed and reported 368 patient samples from June 2, 2025 to September 10, 2025.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on review of urinalysis quality control records (years 2024-2025), and interview with the laboratory testing personnel on September 10, 2025 at 11:45 AM; it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the urinalysis quality control requirements. Refer to D5469.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p> <p>(b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of urinalysis quality control records (years 2024-2025), and interview with the laboratory testing personnel on September 10, 2025 at 11:45 AM; it was determined that the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the urinalysis quality control requirements. Refer to D5469.</p>