Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2304815	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Edmarie 2	Parcela 129-A, Barrio Palomas, Comerio, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clnico Edmarie 2 on June 2, 2026. 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 June 2, 2026.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), hematology Proficiency Testing (PT) scores (year 2025), and interview with the laboratory director (LD) on June 2, 2026, at 9:21 a.m., the laboratory failed to evaluate the accuracy of patient testing for the hematology specialty (Complete Blood Count (CBC) and White Blood Cell (WBC) 5-Parameters testing), when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 813 out of 813 patient samples from June 2025 through November 2025. The findings include: 1. PRPTSP and hematology PT scores were reviewed from February 2025 through March 2026. 2. Review of the hematology PT scores for the third testing event in 2025 showed that the PT provider assigned an artificial score of 100 percent for CBC and WBC 5-Parameters testing. The results were not evaluated. 3. During interview on June 2,2026, at 9:26 a.m., with the LD, the accuracy of the excused hematology specialty (Complete Cell Count -

	(CBC) and White Blood Cell (WBC) 5 Parameters) was required. The LD stated that the laboratory did not evaluate the accuracy of the hematology specialty test. 4. The laboratory processed and reported 813 out of 813 patient samples from June 2025 through November 2025. 5. The LD confirmed on June 2,2026, at 9:40 a.m., that the laboratory did not evaluate and did not have a written procedure to perform that evaluation.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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. This STANDARD is not met as evidenced by: Based on hematology calibration verification records review (years 2025-2026), manufacturer's instructions, and laboratory director (LD) interview on June 2,2026, at 11:30 a.m., the laboratory failed to perform calibration verification procedures for the Cell-Dyn Emerald System at least every six months. The laboratory processed and reported 1,600 out of 1,600 Complete Blood count (CBC) patient specimens during the periods of March 12, 2025, through September 29, 2025, and March 30, 2026, through June 1, 2026. The findings include: 1. The laboratory used the Cell-Dyn Emerald system to perform CBC patient testing. 2. The manufacturer's instructions required the laboratory to perform calibration verification procedures at least every six months. 3. The review of hematology calibration verification records from March 2025 through June 1, 2026, showed that the laboratory did not perform calibration verification at least every six months. The laboratory performed calibration procedures in September 2024 and September 2025. 4. The laboratory processed and reported 1,600 out of 1,600 CBC patient specimens during the periods of March 12, 2025, through September 29, 2025, and March 30, 2026, through June 1, 2026. 5. During interview on June 2, 2026, at 11:50 a.m., the laboratory director confirmed that the laboratory did not perform calibration verification at least every six months.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test

	results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of white blood cells (WBC) differential comparison records (year 2025), and interview with the laboratory director (LD) on June 2, 2026, at 10:20 a.m., the laboratory failed to evaluate and define, twice a year, the relationship of the WBC differential results between the manual microscopic examination method and the Cell-Dyn Emerald system. The laboratory processed and reported 1,603 out of 1,603 Complete Blood Count (CBC) patient specimens during the year 2025. The findings include: 1. The laboratory performed and reported WBC differential results using two methods: manual microscopic examination and the Cell-Dyn Emerald system. 2. On June 2, 2026, at 10:20 a.m., the WBC differential comparison records for the year 2025 were requested. No records were available to show that the laboratory performed twice a year comparison between the manual microscopic examination method and the Cell-Dyn Emerald system. 3. The laboratory processed and reported 1,603 CBC patient specimens during the year 2025. 4. During interview on June 2, 2026, at 10:30 a.m., the LD confirmed that the laboratory did not perform or document twice a year evaluation of the relationship of the WBC differential results between the manual method and the Cell-Dyn Emerald system.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025-2026), hematology proficiency testing (PT) scores (year 2025), laboratory policies and procedures, and interview with the laboratory director on June 2, 2026, at 12:30 p.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with hematology PT requirements. Refer to D5215.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 review of hematology calibration verification records (years 2025-2026), manufacturer's instructions, WBC differential comparison records (year 2025), and laboratory director interview on June 2, 2026, at 12:30 p.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with hematology specialty requirements. Refer to D5439 and D5775.