Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2241409	02/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Marie-E	Calle 47, Bloque 54 # 8, Urb Sierra Bayamon, 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 the Laboratorio Clnico Marie-E on February 12, 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 February 12, 2026.
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 2024-2025), manufacturer's instructions and laboratory general supervisor interview on February

	12, 2026, at 12:00 p.m., the laboratory failed to perform calibration verification procedures at least every six months. The laboratory processed and reported 2,947 Complete Blood Count (CBC) test from October 2025 through January 2026. The findings include: 1. The laboratory used a Mindray BC-5390 hematology system to perform Complete Blood Count (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 calibration verification records from March 2024 through February 2026 showed that the laboratory did not perform calibration verification at least every six months. Documentation showed calibration verification procedures were performed in: March 2024, October 2024, April 2025 and January 2026. 4. The laboratory processed and reported 2,947 Complete Blood Count (CBC) test from October 2025 through January 2026. 5. During interview on February 12, 2026, at 12:15 p.m., the laboratory general supervisor confirmed that the laboratory did not perform calibration verification at least every six months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (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. This STANDARD is not met as evidenced by: Based on a review of Erythrocyte Sedimentation Rate (ESR) quality control (QC) records (years 2024-2025) by MINI-CUBE instrument and the interview with the laboratory general supervisor on February 12, 2026, at 11:45 a.m., the laboratory failed to verify the manufacturer's stated values of the ESR control materials prior to placing new controls lots into routine use. The laboratory processed and reported 456 out of 456 ESR patient samples from January 9, 2024, through February 11, 2026. The findings include: 1. The review of ESR quality control records showed that the laboratory used ESR-Chex Plus (Levels 1 and 2) to monitor the precision of ESR testing on the MINI-CUBE instrument. 2. The review of QC records showed that the laboratory placed the following lots of ESR control materials into routine use without verifying the manufacturer's stated values: a. Control Lot: L1 906 (Level 1 Normal) / L2 906 (Level 2 Abnormal) Use dates: January 9, 2024, through February 22, 2024. Patient samples processed and reported: 39 b. Control Lot: L1 918 (Level 1 Normal) / L2 918 (Level 2 Abnormal) Use dates: February 23, 2024, through May 17, 2024. Patient samples processed and reported: 49 c. Control Lot: L1042 (Level 1 Normal) / L2 042 (Level 2 Abnormal) Use dates: May 21, 2024, through October 28, 2025. Patient samples processed and reported: 284 d. Control Lot: L1138 (Level 1 Normal) / L2 138 (Level 2 Abnormal) Use dates: October 30, 2025, through February 11, 2026. Patient samples processed and reported: 84 3. During the interview on February 12, 2026, at 11:55 a.m., the laboratory general supervisor confirmed that the laboratory placed the ESR control materials into routine use without first verifying the manufacturer's stated values. 4. The laboratory processed and reported 456 out of 456 ESR patient samples from January 9, 2024, through February 11, 2026.

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 quality control records review (years 2024-2025) and interview with the laboratory general supervisor on February 12, 2026, at 1:20 p.m., the laboratory director failed to ensure that the general supervisor complied with the Hematology quality control requirements. Refer to D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on Hematology quality control records review (years 2024-2025) and interview with the laboratory general supervisor on February 12, 2026, at 1:20 p.m., the laboratory general supervisor failed to ensure verification of the manufacturer's stated values for Erythrocyte Sedimentation Rate (ESR) and hematology calibration verification procedures. Refer to D5439 and D5469.