

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0927289	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Laboratorio Clinico Marie E	Street Address, City, State Carr 862 Km 2-7 63b Victoria Heights, 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	<p>The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clinico Marie -E Inc. on May 14, 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 May 14, 2026.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>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 on May 14, 2026, at 9:30 a.m., the laboratory failed to evaluate the accuracy of 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 11,887 patient samples from March 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 second testing event in 2025 showed that the PT provider assigned an artificial score of 100 percent in WBC 5-parameters; and the third testing event in 2025 showed that the PT provider assigned an artificial score of</p>

100 percent for CBC and WBC 5-Parameters. The results were not evaluated. 3. During interview on May 14,2026, at 10:05 a.m., with the laboratory director, the accuracy of the excused hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The laboratory director stated that no procedure for accuracy evaluation was performed. 4. The laboratory director stated on May 14,2026, at 10:05 a.m., that the laboratory did not developed a written procedure to evaluate the accuracy of test not evaluated by the PT provider. 5. The laboratory processed and reported 11,887 patient samples from March 2025 through November 2025.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(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 May 14, 2026, at 2:00 p.m., the laboratory director failed to ensure that the technical supervisor evaluated the accuracy of hematology testing and the laboratory established a written procedure for the evaluation and follow-up of PT events not evaluated by the PT provider. Refer to: D5215.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(2)

(b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system;

This STANDARD is not met as evidenced by:
Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores and interview with the laboratory director on May 14, 2026, at 2:00 p.m., the technical supervisor failed to fulfill her responsibilities and duties to ensure compliance with the hematology PT requirements. Refer to D5215.