

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0993164	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Laboratorio Clinico Emanuel	Street Address, City, State Carr # 2, Km 30 Hm 4, Parcelas 18 C, Vega Alta, 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 Emanuel on September 15, 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 September 15, 2026.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025-2026), Certification and Survey Provider Enhanced Report (CASPER) Report 0155D scores, proficiency laboratory records and interview with the laboratory testing personnel on September 15, 2026 at 9:57 AM, the laboratory failed to take corrective action when obtained an unsatisfactory score for the subspecialty of routine chemistry in the analytes of sodium in the second proficiency testing event of the year 2026. The finding includes: 1. The PRPTSP and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful score: Analyte: Sodium a. Second testing event year 2026 - 60% 2. The laboratory proficiency records were reviewed on September 15, 2026 at 9:38 AM, and showed that the laboratory failed to take corrective action when the unsatisfactory score was received in the following analytes: sodium analyte in the second proficiency testing

	event of the year 2026. 3. The laboratory testing personnel confirmed on September 15, 2026 at 9:57 AM, that the laboratory failed to take corrective action when obtained an unsatisfactory score in the sodium analyte in the second proficiency testing events of the year 2026.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing scores (year 2024), CASPER Report 0155D scores, proficiency laboratory records and interview with the laboratory testing personnel on September 15, 2026 at 9:57 AM, the laboratory failed to take corrective action when obtained an unsatisfactory score in the sodium analyte in the second proficiency testing event of the year 2026. Refer to D2094.