

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2105017	(X3) Date Survey Completed 06/18/2026
Name of Provider or Supplier Laboratorio Clinico Luquillo	Street Address, City, State Bo Fortuna Ii, Calle 13, Parcela # 52, Luquillo, 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 Luquillo on June 18, 2026. 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 June 18, 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), Certification and Survey Provider Enhanced Reports (CASPER Report 0155D) scores, hematology Proficiency Testing (PT) scores (year 2025) and laboratory director interview on June 18, 2026, at 11:02 AM; the laboratory failed to evaluate the accuracy of testing in the hematology specialty, when the laboratory received an artificial score of 100 percent from the PT provider on the 2025 third event (November 2025). The laboratory processed and reported 2,493 Complete Blood Count (CBC) hematology patient samples from June 2025 through June 18, 2026. The findings include: 1. The CASPER Report 0155D scores were reviewed on June 18, 2026 at 11:00 AM, and showed that the laboratory received 100 percent score in the hematology third event of 2025 (November 2025). 2. PRPTSP were reviewed from February 2025 through June 2026. 3. 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. The results were not evaluated. 4. During interview

	with the laboratory director on June 18, 2026, at 11:02 AM; the accuracy of the excused 2025 hematology specialty PT third event (Complete Blood Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The laboratory director stated that no procedure for accuracy evaluation was performed. 5. The laboratory director also stated on June 18, 2026, at 11:07 AM, that no written procedure was developed by the laboratory to evaluate the accuracy of tests not evaluated by the PT provider. 6. From June 2025 through June 18, 2026, the laboratory processed and reported 2,493 hematology CBC patient samples.
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 2025-2026), CASPER Report 0155D scores, proficiency laboratory records and interview with the laboratory director on June 18, 2026 at 11:02 AM, the laboratory director failed to verify the accuracy of the hematology proficiency test when the laboratory obtained an artificial score. Refer to D5215.