

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1052755	(X3) Date Survey Completed 05/08/2026
Name of Provider or Supplier Laboratorio Clinico Sebastian	Street Address, City, State Carr 723 Km 01 Bo Asomante, Aibonito, 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 Clinico Sebastian on May 8, 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 8, 2026.
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 technical supervisor interview on May 8, 2026, at 8:54 A.M.; the laboratory failed to evaluate the accuracy of testing in the hematology specialty when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 3,570 patient samples from June 2025 through May, 2026. The findings include: 1. PRPTSP were reviewed from February 2025 through May 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. The results were not evaluated. 3. During interview On May 8, 2026, at 8:47 A.M.; with the technical supervisor, the accuracy of the excused hematology specialty (Complete Blood Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The technical supervisor stated that no procedure for accuracy evaluation was performed. 4. The laboratory technical supervisor confirmed on May 8, 2026 at 8:54 A.M., the</p>

laboratory did not performed the accuracy evaluation. From June 2025 through May 8, 2026, the laboratory processed and reported 3,570 patient samples.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(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 Service Program (PRPTSP) (year 2025 and 202), Certification and Survey Provider Enhanced Report (CASPER) 0155D scores, proficiency laboratory records and interview with the laboratory technical supervisor on May 8, 2025 at 8:54 A.M, failed to evaluate the accuracy of testing in the hematology specialty when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 3,570 patient samples from June 2025 through May, 2026. Refer to D5215.