

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>40D1047456</p>	<p><b>(X3) Date Survey Completed</b></p> <p>06/09/2026</p>
<p><b>Name of Provider or Supplier</b></p> <p>Laboratorio Clinico Bio Tech</p>	<p><b>Street Address, City, State</b></p> <p>Urb Villa Carolina, Blq 139-12 Calle 401, Carolina, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>The Centers for Medicare &amp; Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clinico Bio Tech on June 9, 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 June 9, 2026.</p>
<p><b>D5215</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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), Certification and Survey Provider Enhanced Reports (CASPER Report 0155D) scores, hematology Proficiency Testing (PT) scores (year 2025) and laboratory director interview on June 9, 2026, at 9:55 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 7,373 patient samples from June 2025 through June 9, 2026. The findings include: 1. The CASPER Report 0155D scores were review on June 9, 2026 at 8:00 AM, and show that the laboratory received 100 percent score in the third event of hematology in the year 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 On June 9, 2026, at 9:</p>

50 A.M.; with the laboratory director, the accuracy of the excused hematology specialty (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 9, 2026, at 9:55 A.M.; that no written procedure was developed by the laboratory to evaluate the accuracy of test not evaluated by the PT provider. 6. From June 2025 through June 9, 2026, the laboratory processed and reported 7,373 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 Service Program (PRPTSP) scores (year 2025-2026), Certification and Survey Provider Enhanced Reports (CASPER Report 0155D) scores, proficiency laboratory records and interview with the laboratory director on June 9, 2026 at 9:55 AM, the laboratory director failed to verify the accuracy of the hematology proficiency test when the laboratory obtained an artificial score. Refer to D5215.