

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D2257064	<b>(X3) Date Survey Completed</b> 04/21/2026
<b>Name of Provider or Supplier</b> Laboratorio Clinico Lavita	<b>Street Address, City, State</b> Carr 2 Km 160 Hm 9 Local 4, Hormigueros, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2026), hematology Proficiency Testing (PT) scores (year 2025) and general supervisor interview on April 21, 2026 at 10:00 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 1,451 patient samples from July 2025 through April 21, 2026. The findings include: 1. PRPTSP were reviewed from February 2025 through March 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 April 21, 2026, at 10:00 a.m., with the general supervisor, the accuracy of the excused hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The general supervisor stated that no procedure for accuracy evaluation was performed. 4. The general supervisor on April 21, 2026 at 10:15 a.m, also stated that no written procedure was developed by the laboratory to evaluated the accuracy of test not evaluated by the PT provider. 5. From July 2025 through April 21, 2026 the laboratory processed and reported 1.451 patient samples.</p>
<b>D6091</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iii)</p> <p>(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</p>

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 2026), proficiency laboratory records (2025-2026) and interview with the laboratory general supervisor on April 21, 2026 at 10:15 A.M., it was determined that the laboratory director 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. Refer to D5211.