

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0965124	<b>(X3) Date Survey Completed</b>  04/04/2025
<b>Name of Provider or Supplier</b>  Laboratorio Avanzado Emmanuel	<b>Street Address, City, State</b>  Carretera Pr-693, Km 7, Hm 6, Local 1-B Mahi Mahi, Dorado, 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>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Avanzado Emmanuel on April 3, 2025. 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 April 3, 2025.
<b>D2104</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing (PRPT) event scores (years 2023-2024), CASPER Report 0155D, PRPT (year 2024) schedule and laboratory director interview on April 4, 2025, at 9:10 A.M., it was determined that the laboratory failed to report the Human Chorionic Gonadotropin (hCG) proficiency testing results within the time frame established by the program. The findings include: 1. The PRPT and CASPER Report were reviewed on April 4, 2025, at 9:10 A.M., from February 2023 to December 2024. 2. The PRPT schedule for the year 2024 showed that the deadline of the third testing event for Endocrinology scores was October 25, 2024. (Reviewed on April 4, 2025, at 9:15 A.M.) 3. Review of the PRPT scores showed that the laboratory obtained a 0% score in the third testing event, year 2024, for hCG tests. (Reviewed on April 4, 2025, at 9:20 A.M.) 4. The laboratory director confirmed on April 4, 2025, at 9:30 A.M., that the laboratory failed to report the hCG proficiency testing results of the third testing event within the time frame established by the PRPT.</p>

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(ii)

(e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program;

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing scores (years 2023-2024) and CASPER Report and laboratory director interview on April 4, 2025, at 10:30 A.M, it was determined that the laboratory director failed to report the Endocrinology proficiency testing results within the time frame established by the program, getting a score of 0% in the third event for hCG.