

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658189	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Ponce Clinical Laboratory Inc	Street Address, City, State 609 Ave Tito Castro Ste 101, Ponce, 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 Ponce Clinical Lab, Inc. on March 26, 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 March 26, 2025.
D2093	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 scores (year 2024), CASPER Report 0155D scores and laboratory director interview on March 26, 2025 at 10:30 AM, it was determined that the laboratory failed to participate in the routine chemistry second testing event performed on May 2024. The findings include: 1. The proficiency testing records were reviewed from January 2023 to December 2024. Reviewed on March 26, 2025 at 10:30 AM. 2. The laboratory did not participate in the second testing event for routine chemistry (routine chemistry, urinalysis, urine sediment) performed in May 2024, a testing score of 0 % as obtained. Review on March 26, 2025 at 11:00 AM. 3. The deadline of the second testing event report of routine chemistry was May 23, 2024. 4 The laboratory director confirmed on March 26, 2025 at 11:10 AM, that the laboratory failed to participate in the second testing event of routine chemistry specialty in May 2024.</p>
D2104	<p>ENDOCRINOLOGY CFR(s): 493.843(d)</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.

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing scores (year 2024), CASPER Report 0155D scores and laboratory director interview on March 26, 2025 at 10:30 AM, it was determined that the laboratory failed to participate in the endocrinology second testing event performed on May 2024. The findings include: 1. The proficiency testing records were reviewed from January 2023 to December 2024. Reviewed on March 26, 2025 at 10:30 AM. 2. The laboratory did not participate in the second testing event for endocrinology (human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), thyroxine (T4), triiodothyronine (T3) and Free T4 (thyroxine) performed in May 2024, a testing score of 0 % as obtained. Review on March 26, 2025 at 11:00 AM. 3. The deadline of the second testing event report of endocrinology was May 23, 2024. 4 The laboratory director confirmed on March 26, 2025 at 11:10 AM, that the laboratory failed to participate in the second testing event of endocrinology subspecialty in May 2024.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of Puerto Rico Proficiency Testing scores (year 2024), CASPER Report 0155D scores and laboratory director interview on March 26, 2025 at 10:30 AM, it was determined that the laboratory director failed to ensure that the technical consultant would participate during the second testing event of year 2024 of proficiency testing samples.. Refer to D2093 and D2104.