

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658052	(X3) Date Survey Completed 11/13/2025
Name of Provider or Supplier Laboratorio Clinico Canovanas	Street Address, City, State Calle Palmer # 8, Esq Calderon Mojica, Canovanas, 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 Canovanas on November 13, 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 November 13, 2025.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) (year 2024 and 2025), Certification and Survey Provider Enhanced Report (CASPER) Report 0155D scores, proficiency laboratory records and interview with the laboratory director on November 13, 2025 at 9:50 AM, it was determined that the laboratory failed to take corrective action when obtained an unsatisfactory score for the subspecialty of routine chemistry in the analyte of sodium in the third proficiency testing event of the year 2024. The finding includes: 1. The PRPTSP and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: sodium a. third testing event year 2024 - 60% 2. The laboratory proficiency records were reviewed on November 13, 2025 at 9:23 AM, and showed that the laboratory failed to take corrective action when the unsatisfactory score was</p>

received. in the sodium analyte in the third proficiency testing event of the year 2024.
3. The laboratory director confirmed on November 13, 2025 at 9:50 AM, that the laboratory failed to take corrective action when obtained an unsatisfactory score in the sodium analyte in the third proficiency testing event of the year 2024.

D2128

HEMATOLOGY
CFR(s): 493.851(e)

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) (year 2024 and 2025), Certification and Survey Provider Enhanced Report (CASPER) Report 0155D scores, proficiency laboratory records and interview with the laboratory director on November 13, 2025 at 9:50 AM, it was determined that the laboratory failed to take corrective action when obtained an unsatisfactory score in cell identification in the hematology specialty for the first proficiency testing event of the year 2025. The finding includes: 1. The PRPTSP and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: cell identification in the hematology specialty a. first testing event year 2025 - 70% 2. The laboratory proficiency records was reviewed on November 13, 2025 at 9:23 AM, and showed that the laboratory failed to take corrective action when obtained an unsatisfactory score in the cell identification in the hematology specialty for the first proficiency testing event of the year 2025. 3. The laboratory director confirmed on November 13, 2025 at 9:50 AM, that the laboratory failed to take corrective action when obtained an unsatisfactory score in the cell identification in the hematology specialty for the first proficiency testing event of the year 2025.

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 2024 and 2025), Certification and Survey Provider Enhanced Report (CASPER) 0155D scores, proficiency laboratory records and interview with the laboratory director on November 13, 2025 at 9:50 AM, it was determined that the laboratory director failed to take corrective action when obtained the unsatisfactory score in the proficiency testing event of the year 2024 and 2025. Refer to D2094, D2128.