

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0722888	(X3) Date Survey Completed 08/16/2024
Name of Provider or Supplier Laboratorio Clinico Miraflores	Street Address, City, State Ave Los Dominicos # 6 Bloque 14, Bayamon, 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 announced CLIA recertification survey at Laboratorio Clinico Miraflores on August 16,2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the announced routine CLIA recertification survey ending on August 16, 2024.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(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 Puerto Rico Proficiency Testing (PRPT) scores review (year 2023-2024) and laboratory general supervisor interview on August 16, 2024 at 9:40 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory result for serum creatinine test during the second testing event of year 2023. The findings include: 1. Proficiency testing scores reviewed from February 2023 to May 2024. (Review on August 16, 2024 at 9:25 A.M.) 2. The PRPT scores review on August 16, 2024 at 9:40 A.M. , showed that the laboratory did not take nor document corrective actions when it obtained an unsatisfactory result of 40% for serum creatinine test in the second testing event performed in May 2023. 3. The laboratory general supervisor confirmed on August 16, 2024 at 9:50 A.M., that the laboratory did not take nor document corrective actions when it obtained an unsatisfactory result for serum creatinine test.</p>

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program scores (year 2023-2024) and laboratory director interview on August 16, 2024 at 1:17 P.M., it was determined that the laboratory director did not ensure that corrective actions were taken when the laboratory obtained 40 % score for serum creatinine test in the second testing event of year 2023. Refer to D2094.