Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2273597	(X3) Date Survey Completed 10/18/2024
Name of Provider or Supplier Laboratorio Clinico Oscar, Inc	**Street Address, City, State** Calle Corchado # 58, 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 Laboratorio Clnico Oscar on October 18, 2024. Thelaboratory 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 October 18, 2024.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(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 Puerto Rico Proficiency Testing Program scores review and laboratory general supervisor interview on October 18, 2024 at 9:17 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory testing score for creatinine analyte. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) scores were reviewed from April 2023, to May 2024, on October 18, 2024 at 9:08 AM. 2. Review of Proficiency Testing scores showed that the laboratory obtained unsatisfactory scores of 40 % percent for creatinine on the second event in May 2023. No remedial actions were taken nor documented. 3. On October 18, 2024 at 9:17 AM, the laboratory supervisor confirmed that the laboratory fail to take corrective action when the laboratory obtained unsatisfactory score for creatinine.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory director interview on October 18, 2024 at 10:20 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel, general supervisor and clinical consultant competence evaluation. The findings include: 1. The laboratory schedule for testing personnel, general supervisor and clinical consultant competence evaluation showed that it must be performed every year. 2. The laboratory did not perform the testing personnel, general supervisor and clinical consultant competence evaluation since April 2023. 3. The laboratory director confirmed on October 18, 2024 at 10:20 AM, that the competence evaluations were not performed as established.
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 (PRPTP) scores review and laboratory director interview on October 18, 2024 at 11:22 AM; it was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained unsatisfactory scores. Refer to D 2094. The findings include: 1. The laboratory director did not ensure that a corrective actions were taken when the laboratory obtained unsatisfactory scores.