Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2089661	**(X3) Date Survey Completed** 06/10/2025
Name of Provider or Supplier Plaza Del Carmen Medical Services Inc	**Street Address, City, State** Carr 891, Km 1 Hm 7 Bo Pueblo, Corozal, 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 Clnico Plaza del Carmen Medical Services Inc. on June 10, 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 June 10, 2025.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on Urinalysis quality control records review and interview with the laboratory general supervisor on June 10, 2025, at 11:30 A.M; it was determined that the laboratory did not include or document a positive and negative microscopic sediment control material when 1145 out of 1145 patient samples were processed and reported for manual microscopic from January 2024 to June 9, 2025. The findings include : 1. The urinalysis quality control records were reviewed on June 10, 2025, at 11:30 AM. 2. The quality control records showed that the laboratory did not performed or document the positive and negative control material for the microscopic sediment urinalysis. 3. The laboratory general supervisor confirmed on June 10, 2025, at 12:00 PM; that the laboratory did not performed the quality control records for manual microscopic urinalysis examinations. 4. The laboratory processed and reported 1145 out of 1145 patient specimens for urinalysis sediment between January 2024 to June 9, 2025.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on Urinalysis quality control records review (years 2024 and 2025), and interview with the laboratory general supervisor on June 10, 2025, at 12:30 PM; it was determined that the laboratory director failed to ensure compliance with the analytic requirements for microscopic sediment control each day of patients testing. Refer to D5449.