Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2126577	**(X3) Date Survey Completed** 10/25/2023
Name of Provider or Supplier Metro Pavia Clinic - Aguadilla	**Street Address, City, State** Carretera 107 Barrio Camaseyes, Aguadilla, 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**
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the Urinalysis quality control review and interview with the laboratory general supervisor on October 25, 2023 at 11:45 AM; it was determined that the laboratory did not include or document any negative microscopic sediment control material when 712,909 patient's were processed and reported under the microcope since January 2022. The findings include: a. The Urinalysis quality control was reviewed on October 25, 2023 at 11:45 AM, and showed that the laboratory did not include or document any negative microscopic control for sediment. b. The laboratory testing personnel confirmed on October 25, 2023 at 11:50 AM that no microcopy control was implemented since January 2022 when 12.909 patient's were processed and reported under the microcope since January 2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 2022-2023) and laboratory general supervisor interview on October 25, 2023 at 11:45 A. M, it was determined that the laboratory director failed to ensure that the laboratory included a negative microscopic sediment control material when 12,909 patient's samples were processed and reported under the microscope since January 2022. The finding include: 1. The laboratory did not include or document any negative microscopic sediment control material when 12,909 patient's were processed and reported under the microcope since January 2022. Refer to D5445.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2022-2023) and laboratory director interview on October 25, 2023 at 11:45 A. M, it was determined that the laboratory general supervisor failed to ensure that the laboratory included a negative microscopic sediment control material when 12,909 patient's samples were processed and reported under the microscope since January 2022. Refer to D5445.