Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2175066	**(X3) Date Survey Completed** 10/03/2024
Name of Provider or Supplier Laboratorio Metro Pavia Clinic Luquillo	**Street Address, City, State** Carr # 3, Km 32 Bo Mameyes, Luquillo, 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 Metro Pavia Clinic Luquillo on October 3, 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 3, 2024.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration records, manufacturer's instructions, and laboratory supervisor interview on October 3, 2024 at 10:56 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the XS-1000i hematology system. The laboratory processed and reported 4,614 patient samples in the year 2023. The findings include: 1. The laboratory uses a XS-1000i hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures every six months. 3. On October

	3, 2024 at 10:38 AM, the calibration records of XS-1000i hematology system showed that the laboratory did not perform at least every 6 months the calibration verification procedures of the 2023 year. In the year 2023 the laboratory performed the calibration on April 17, 2023 and the next calibration was performed on April 17, 2024. The laboratory supervisor stated that the calibration verification must be performed on November. 4. The laboratory supervisor confirmed on October 3, 2024 at 10:56 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the XS-1000i hematology system.
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 the hematology specialty and interview with the laboratory supervisor on October 3, 2024 at 11:00 AM, it was determined that the laboratory director failed to ensure the compliance with the quality control program. Refer to D5437.