Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2160526	(X3) Date Survey Completed 12/20/2019
Name of Provider or Supplier Metro Pavia Clinic Bella Vista	**Street Address, City, State** Urb Bella Vista, Marginal 167 Ad-10, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of validation records for the urine microscopic examination, urine microscopic examination reports records reviewed and interview with the technical supervisor at 11:22 AM on December 20, 2019, it was determined that the laboratory failed to perform the validation for the urine microscopic examination procedure before reporting 783 out of 783 patient's urine microscopic examination results from June 19, 2019 to December 19, 2019. The findings include: 1. The laboratory did not perform the validation of the urine microscopic examination procedure. 2. On December 20, 2019 at 11:22 AM , the urine microscopic examination reports showed that the laboratory reported 783 out of 783 patient's urine microscopic examination results from June 19, 2019 to December 19, 2019. 3. The technical supervisor confirmed at 11:22 AM on December 20, 2019, that the laboratory did not validated the urine microscopic examination procedure.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of validation records for the urine microscopic examination, urine microscopic examination reports records reviewed and interview with the technical supervisor at 11:22 AM on December 20, 2019, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the urine microscopic examination procedure. Refer to D 5421.