Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2001687	**(X3) Date Survey Completed** 02/13/2018
Name of Provider or Supplier Metro Pavia Clinic Ponce	**Street Address, City, State** Calle Marina Num 38, Ponce, 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 review of thyroxin free (T4 free) test validation records, T 4 free testing records review and technical supervisor interview on February 13, 2018 at 10:50 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new T 4 free test performed by the Vitros ECI system, before reporting 1,113 out of 1,113 patient T 4 free test results from March 16, 2017 to February 12, 2018. The findings include: 1. The thyroxin free (T 4 free) test validation records showed that the laboratory validated the new T 4 free test on February 28, 2017 by the Vitros ECI system. 2. The thyroxin free (T 4 free) test validation records showed that the laboratory laboratory did not verify that the manufacturer's T 4 free reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient T 4 free test results. 3. The technical supervisor confirmed on February 13, 2018 at 10:55 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient T 4 free test results. 4. The T 4 free testing records showed that the laboratory processed and reported 1,113 out of 1,113 patients T 4 free specimens from March 16, 2017 to February 12, 2018.

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 review of thyroxin free (T4 free) test validation records, T 4 free testing records review and technical supervisor interview on February 13, 2018 at 10:50 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the T 4 free test performed by the Vitros ECI system, before reporting 1,113 out of 1,113 patient T 4 free test results from March 16, 2017 to February 12, 2018. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirements of T 4 free test . Refer to D 5421. (The laboratory did not complete the evaluation of the performance specifications of the new T 4 free test performed by the Vitros ECI system, before reporting 1,113 out of 1,113 patient T 4 free test results from March 16, 2017 to February 12, 2018).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of thyroxin free (T4 free) test validation records, T 4 free testing records review and technical supervisor interview on February 13, 2018 at 10:50 AM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems of T4 free tests, before reporting 1,113 out of 1,113 patient T 4 free test results from March 16, 2017 to February 12, 2018. Refer to D 5421 ((The laboratory did not complete the evaluation of the performance specifications of the new T 4 free test performed by the Vitros ECI system, before reporting 1,113 out of 1,113 patient T 4 free test results from March 16, 2017 to February 12, 2018).