Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0985371	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Metro Pavia Clinic Bayamon	Santa Cruz St #77, 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
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2018 and 2019) and general supervisor interview on August 6, 2019 at 12:00 PM, it was determined that the laboratory failed to report within the time frame specified by the program, the hematology proficiency testing results of the first event of the year 2019. The findings include: 1. On August 6, 2019 at 12:00 PM, the PRPTP records showed that the laboratory obtained a score of 0 percent for the first hematology proficiency testing (PT) event (March, 2019) due to the laboratory did not report the PT results within the time frame specified by the program. 2. The general supervisor confirmed on August 6, 2019 at 12:00 PM, that the the laboratory obtained a score of 0 percent for the first hematology proficiency testing (PT) event (March, 2019) . He stated that he reported the PT results on time but he forgot to submit the results to the PRPTP.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by:

	Based on lack of preventive maintenance of the laboratory centrifuge and interview with the general supervisor on August 6, 2019 at 10:20 AM, it was determined that the laboratory failed to retain the centrifuge's preventive maintenance records since January, 2018. The findings included: 1. The laboratory did not have available the laboratory centrifuge's preventive maintenance (cleaning or preventive maintenance as needed) records since January, 2018. 2. The general supervisor confirmed on August 6, 2019 at 10:20 AM, that the laboratory did not have available the centrifuge's preventive maintenance records.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel file records review and general supervisor interview on August 6, 2019 at 12:30 AM, it was determined that the laboratory failed to follow the written policies to assess the competency of the 2 shift testing personnel since January 2018. The findings include: 1. On August 6, 2019 at 12:30 AM, the 4 out 4 personnel file records of the 2 shift testing personnel showed that the laboratory did not evaluate the competence of these personnel since January 2018. 2. The general supervisor confirmed on August 6, 2019 at 12:30 AM, that the laboratory did not evaluate the the competence of the 2 shift testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review and general supervisor interview on August 6, 2019 at 12:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems: personnel competence. Refer to D 5209 (The laboratory did not evaluate the competence of the 2 shift testing personnel).
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: 1. Based on review of validation records of the Vitros 5600 system and general supervisor interview on August 6, 2019 at 9:15 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,786 patient results for follicle-stimulating hormone (FSH) test and reporting 1,041 patients results for leuteinizing hormone (LH) test from March 18, 2019 to August 5, 2019. The findings include: a. On August 6, 2019 at 9:15 AM, the Vitros 5600 system validation records showed that the laboratory laboratory performed the validation procedures for FSH and LH tests on October 30, 2018. However, the laboratory did not verify that the manufacturer's FSH and LH tests reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patient results from March 18, 2019 to August 5, 2019. b. The general supervisor confirmed on August 6, 2019 at 9:15 AM, that the laboratory did not verify that the manufacturer's FSH and LH tests reference intervals (normal values) before reporting patients results. c. The laboratory processed and reported 1,786 patients specimens for FSH and 1,041 patients specimens for LH from March 18, 2019 to August 5, 2019. 2. Based on review of validation records of the Vitros 5600 system and general supervisor interview on August 6, 2019 at 9:15 AM, it was determined that the laboratory failed to complete the verification of the performance specifications for the new ALT-V tests before reporting 19, 106 patient test results from March 6, 2019 to August 5, 2019. The findings include: a. On August 6, 2019 at 9:15 AM, the Vitros 5600 system validation records showed that the laboratory maintained the raw data of the ALT-V tests validation that it was performed on January 24, 2019. However, the laboratory did not verify statistically the following performance characteristics of this new test: accuracy, precision and reportable range before reporting patient test results from March 6, 2019 to August 5, 2019. b. The general supervisor confirmed on August 6, 2019 at 9:15 AM, that the laboratory did not have available the evaluation of the ALT-V tests validation. c. The laboratory processed and reported 19, 106 patient specimens for ALT-V test from March 6, 2019 to August 5, 2019.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on lack of preventive maintenance of the laboratory centrifuge and interview with the general supervisor on August 6, 2019 at 10:20 AM, it was determined that the laboratory director failed to ensure that the laboratory retained preventive maintenance record for at least 2 years. Refer to D 3031.

D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records reviewed (years 2018 and 2019) and general supervisor interview on August 6, 2019 at 12:00 PM, it was determined that the laboratory director failed to ensure that the PT results are returned within the timeframes established by the proficiency testing program. Refer to D 2127.
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 review of validation records of the Vitros 5600 system and general supervisor interview on August 6, 2019 at 9:15 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the following tests: FSH, LH and ALT-V from March 6, 2019 to August 5, 2019. Refer to D 5421 (1) (The laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,786 patient results for follicle-stimulating hormone (FSH) test and reporting 1,041 patients results for leuteinizing hormone (LH) test from March 18, 2019 to August 5, 2019). Refer to D 5421 (2) (The laboratory did not complete the verification of the performance specifications for the new ALT-V tests before reporting 19, 106 patient test results from March 6, 2019 to August 5, 2019).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment (QA) records review and general supervisor interview on August 6, 2019 at 12:30 AM, it was determined that the laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D 5291 (The laboratory did not follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems: personnel competence).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel records files review and general supervisor interview on August 6, 2019 at 12:30 PM, it was determined that the laboratory director failed to ensure that 3 out of 4 testing personnel of the 2 shift have the appropriate training prior to testing patients' specimens since January 2018. The findings include: 1. On August 6, 2019 at 12:30 PM, the personnel file showed that 3 out of 4 testing personnel of the 2 shift did not have have the appropriate training prior to testing patients' specimens since January 2018. 2. The general supervisor confirmed on August 6, 2019 at 12:30 PM, that those personnel file did not include the in service training documented.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records files and interview with the general supervisor on August 6, 2019 at 12:30 PM, it was determined that the laboratory director did not specify in writing the duties of the clinical consultant since November 2, 2018. The finding includes: 1. The new clinical consultant was hired on November 2, 2018. However, her personnel files did not include written duties and responsibilities. 2. The general supervisor confirmed on August 6, 2019 at 12:30 PM, that the clinical consultant personnel file did not include the written duties and responsibilities.
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 review of validation records of the Vitros 5600 system and general supervisor interview on August 6, 2019 at 9:15 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting the following tests results: FSH, LH and ALT-V from March 6, 2019 to August 5, 2019. Refer to D 5421 (1) (The laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population before reporting 1,786 patient results for follicle-stimulating hormone (FSH) test and reporting 1,041 patients results for leuteinizing hormone (LH) test from March 18, 2019 to August 5, 2019). Refer to D 5421 (2) (The laboratory did not complete the verification of the performance specifications for the new ALT-V tests before reporting 19, 106 patient test results from March 6, 2019 to August 5, 2019).