Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2160526	07/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Metro Pavia Clinic Bella Vista	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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, quality control records review and testing personnel interview on July 21, 2021 at 12:55 PM, it was determined that the laboratory used the Wright stain reagent with exceeded expiration date when 10 out of 10 patients smears were stained and examined from July 1, 2021 to July 19,2021. The findings include: 1. On July 21, 2021 at 12:55 PM, the Wright stain reagent was observed at the hematology area (lot 9780-00 Exp. 06/30/2021). 2. The quality control records showed that the laboratory used the Wright stain reagent with exceeded expiration date from July 1, 2021 to July 19,2021. 3. The testing personnel confirmed on July 21, 2021 at 12:55 PM, that the laboratory used the Wright stain reagent with exceeded expiration date from July 1, 2021 to July 19,2021. 4. The laboratory stained and examined 10 out of 10 patients smears with the Wright stain reagent (lot 9780-00 Exp. 06/30/2021) from July 1, 2021 to July 19,2021.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on written procedures, preventive maintenance records (years 2020 and 2021) review and interview with the laboratory director on July 21, 2021 at 12:20 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of cobas c 311 analyzer when 1,716 out of 1,716 patient's specimens for comprehensive metabolic panel (CMP) tests were processed from 12/01/2020 to 07/20 /2021. The findings include: 1. On July 21, 2021 at 12:20 PM, the cobas c 311 analyzer preventive maintenance records showed that the laboratory did not perform in the manufacturer's required frequency the every 2 months nor the quarterly preventive maintenance of the cobas c 311 analyzer from 12/01/2020 to 07/20/2021. 2. The laboratory director confirmed on July 21, 2021 at 12:20 PM, that the preventive maintenance records showed that the laboratory did not follow the manufacturer instruction for the every 2 months and the quarterly preventive maintenance procedures for the cobas c 311 analyzer. 3. The laboratory processed 1,716 out of 1,716 patient's specimens for CMP tests from 12/01/2020 to 07/20/2021.
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 observation, quality control records, preventive maintenance records (years 2020 and 2021) review, testing personnel and laboratory director interview on July 21, 2021 at 12:55 PM, it was determined that the laboratory director failed to comply with the requirements for hematology and routine chemistry tests. Refer to D 5417 (The laboratory used the Wright stain reagent with exceeded expiration date when 10 out of 10 patients smears were stained and examined from July 1, 2021 to July 19,2021). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of cobas c 311 analyzer when 1,716 out of 1,716 patient's specimens for comprehensive metabolic panel (CMP) tests were processed from 12/01 /2020 to 07/20/2021).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on observation, quality control records, preventive maintenance records (years 2020 and 2021) review, testing personnel and laboratory director interview on July 21, 2021 at 12:55 PM, it was determined that the testing personnel failed to follow quality control procedures for hematology and routine chemistry tests. Refer to D 5417 (The laboratory used the Wright stain reagent with exceeded expiration date when 10 out of 10 patients smears were stained and examined from July 1, 2021 to July 19,2021). Refer to D 5429 (The laboratory failed to follow written instructions for the

	preventive maintenance of cobas c 311 analyzer when 1,716 out of 1,716 patient's specimens for comprehensive metabolic panel (CMP) tests were processed from 12/01 /2020 to 07/20