Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0985371	09/29/2021
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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma pneumonia manufacturer ' s instructions, Mycoplasma pneumoniae patient testing records review on September 29, 2021 at 11: 33 AM, it was determined that the laboratory failed to follow the manufacturer ' s instructions regarding temperature range when patient's specimens were tested for Mycoplasma pneumoniae by Immuno Card Meridian method from January 3, 2021 to September 24, 2021. The findings include: 1. The manufacturer ' s instruction establishes to perform the test procedures at room temperature from 22 C to 25 C. 2. The Mycoplasma testing records showed that the laboratory did not follow the manufacturer's instruction. 3. The quality control records showed that 120 days out of 265 days the laboratory temperature was out of the manufacturer's temperature established range (22C-25C) . 4. A total of 332 out of 677 patient's test were performed outside the established manufacturer's temperatures range.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control

	materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on routine chemistry (GlycoHemoglobin, Microalbumin test) and Endocrinology (T4, TSH, T3 UP, FT4, PSA test) quality control record random review and the general laboratory supervisor interview on September 29, 2021 at 9:00 a.m. it was determined that the laboratory did not take and document any corrective action when the control value fails below the established mean. The findings include : 1. The FT4 control records (level free 2) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for FT 4 test was 1.52 ng/dL. The Levey-Jennings graph showed that on twenty six out of twenty six days of patient testing the control values were above the established mean. 2. The TT4 control records (level free 2) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for TT 4 test was 6.84 ug/dL. The Levey-Jennings graph showed that on seventeen out of seventeen days of patient testing the control values were above the established mean. 3. The PSA control records (level PSA/1) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for PSA test was 2.49 ng/mL. The Levey-Jennings graph showed that on twenty five out of twenty five days of patient testing the control values were below the established mean. 4. The TSH control records (level THYR-1) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for TSH test was 0.40 mIU/L. The Levey-Jennings graph showed that on eight out of eight days of patient testing the control values were below the established mean. 5. The T3up control records (level THYR-3) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for T3 up test was 46.70 %. The Levey-Jennings graph showed that on seven out of seven days of patient testing the control values were above the established mean. 6. The A1c control records (level GLICO2) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for A1c test was 10.28 % NGSP. The Levey-Jennings graph showed that on twenty seven out of twenty seven days of patient testing the control values were below the established mean. 7. The mALB control records (level free 2) were reviewed from may 1 2021 to may 31, 2021. The laboratory established mean for mALB test was 87.00 mg/L. The Levey-Jennings graph showed that on twenty six out of twenty six days of patient testing the control values were below the established mean 8. The laboratory general supervisor confirm by interview by phone on September 29, 2021 at 9:00 AM, that the laboratory did not evaluate , document or take remedial actions when the quality control results showed deviations (outliers, shift or tends).
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 routine chemistry and general immunology quality control records review and laboratory general supervisor interview on September 29, 2021 at 1:33 PM, it was determined that the laboratory director did not assure that quality control requirements were maintained for general immunology and endocrinology test analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer ' s instructions when perform Mycoplasma pneumoniae test. Refer to D 5405. (Temperature out) 2. The laboratory did not take nor document any corrective action when the control value fails below or above the established mean. Refer to D 5469.