Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1102872	09/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Metropolis	Carr-Pr-860, Km 0, Hm 9, Hg -25, Carolina, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on daily checks records of temperatures (years 2022 and 2023) and interview with the laboratory director on September 13, 2023 at 11:15 AM; it was determined that the laboratory failed to monitor and document the freezer temperature where the laboratory keeps patient samples that will be referred to another laboratory to be processed. The findings include: 1. On September 13, 2023 at 11:00 AM; the daily checks were reviewed and showed that the freezer temperature was not available. The freezer was inspected and there was no thermometer there at the time of inspection. 2. On September 13, 2023 at 11:15 AM; the laboratory director stated that they only use the freezer to keep the samples that will be referred to another laboratory to be processed and confirmed that there was no thermometer inside. Also the laboratory director confirmed that the laboratory failed to monitor and document the frezeer temperature (years 2022 and 2023).
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on General Immunology (Mycoplasma pneumoniae test by Immunocard) quality control records review (years 2022-2023) and laboratory director interview on September 13, 2023 at 11:57 AM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. From January 14, 2023 to September 12, 2023 the laboratory process and report 299 out of 307 patient samples. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records was review on September 13, 2023 at 11:33 AM, and showed that the laboratory did not include the external positive and negative control material each day of patient testing since January 14, 2023. 2. The laboratory director confirmed on September 13, 2022 at 11:57 AM, that the laboratory failed to include a external negative and positive control material each day of patient testing. From January 14, 2023 to September 12, 2023 the laboratory process and report 299 out of 307 patient samples.
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: 1. Based on Mycoplasma pneumoniae quality control records review years 2022 and 2023, and interview with the laboratory director on September 13, 2023 at 11:57 AM, it was determined that the laboratory director (sole personnel) fail to establish the quality control program of the Mycoplasma pneumoniae tests. Refer to D5449. 2. Based on daily checks records years 2022 and 2023 and interview with the laboratory director on September 13, 2023 at 11:15 AM, it was determined that the laboratory director failed to established a range of temperature for freezer where the laboratory keeps patient samples that will be referred to another laboratory to be processed. Refer to 5311.