Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0963573	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Melania	Carr Pr-3, Km 142, Hm 3, Sector Melania,, Guayama, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LABORATORIO CLINICO MELANIA on July 17, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on July 17, 2024.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on manufacturer's instructions, syphilis serology quality control records review (year 2023-2024) and laboratory general supervisor interview at 11:39 A.M. on July 17, 2024, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR (Rapid plasma reagin) method, when 71 out of 82 patient's specimens were processed and reported for RPR (Rapid plasma reagin) test from January 5, 2024, to July 15,2024. The findings include: 1. The laboratory uses the ASI RPR to perform the RPR syphilis qualitative tests. (Reviewed on April 24,2024 at 11:39 A.M.) 2. On July 17 ,2024 at 11:45 A.M., the ASI RPR manufacturer's instructions were reviewed. The manufacturers establishes that the RPR test must be performed at room temperature between 20 C to 30 C. 3. On July 17,2024 at 11:50 A.M., the syphilis serology quality control records review showed that the laboratory processed and reported 71 out of 82 patient's specimens for RPR test from January 5,2024 to July 15,2024, with a temperature range within 19.1C to 19.9C 4. The laboratory general supervisor

	confirmed during interview on July 19,2024, at 12:00 P.M., that the laboratory processed patient's samples outside the established temperature range by manufacturer. B. Based on ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing record review (years 2023-2024), and laboratory general supervisor interview on July 17, 2024, at 12:30 P.M., it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 93 out of 93 patient's specimens were processed and reported for Mycoplasma pneumoniae from November 28, 2023, to July 15,2024. The findings include: 1. The laboratory uses the ImmunoCard Mycoplasma Test Kit to perform the Mycoplasma pneumoniae qualitative tests. (Reviewed on July 17,2024 at 12:30 P.M.) 2. On July 17,2024 at 12: 35 P.M., the ImmunoCard Mycoplasma manufacturer's instructions were reviewed. The manufacturer's instructions established to perform the Mycoplasma pneumoniae test procedures between 22C to 25 range temperature. 3. On July 17,2024 at 12:45 P. M., the Mycoplasma pneumoniae testing records review showed that the laboratory processed and reported 93 out of 93 patient's specimens for Mycoplasma pneumoniae test from November 28, 2023, to July 15,2024, with a temperature range within 19.1C to 21.3C 4. The laboratory general supervisor confirmed during interview on July 17,2024, at 1:00 P.M., that the laboratory processed patient's samples outside the established temperature range by manufacturer.
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 RPR and Mycoplasma pneumoniae manufacturer's instructions, syphilis serology and Mycoplasma pneumoniae testing records and laboratory general supervisor interview on July 14,2024, at 1:45 P.M .,it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. Refer to D5411.
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 RPR and Mycoplasma pneumoniae manufacturer's instructions, syphilis serology and Mycoplasma pneumoniae testing records and laboratory general supervisor interview on July 14,2024, at 1:45 P.M .,it was determined that the general supervisor (testing personnel) not assure that the manufacturer's instructions regarding to the established temperature range for RPR and Mycoplasma pneumoniae test's, when the laboratory processed and reported 77 out of 90 patient's for RPR test and 93 out of 93 patient's specimens for Mycoplasma pneumoniae. Refer to D5411.