Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0668987	01/19/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Morovis	Calle Del Carmen # 20, Morovis, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on ImmunoCard Mycoplasma pneumoniae (Meridian) manufacturer's instructions, Mycoplasma pneumoniae testing records review (years 2022-2023) and general supervisor interview on January 19, 2024, at 12:55 PM, it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 213 out of 235 days of year 2023 performed mycoplasma specimens outside the established temperature range between 18C to 21.9C and 25.3C to 26.1C. The findings include: 1. The laboratory uses ImmunoCard Mycoplasma (Meridian) to perform Mycoplasma patient's samples tests. (Reviewed on January 19, 2024, at 12:55 PM) 2. The ImmunoCard Mycoplasma (Meridian) manufacturer's instructions establish that the Mycoplasma test must be performed at room temperature between 22 C to 25 C. (Reviewed on January 19, 2024, at 1:00 PM) 3.On January 19,2024 at 1:10 PM, the Mycoplasma pneumoniae testing records review showed that from January 9,2023 to December 29,2023, the laboratory processed and reported 942 out of 1052 patient's specimens with a temperature range between 18 to 21.9C and 25.3 to 26.1C 4.The general supervisor confirmed during interview, on January 19,2024 at 1:30 PM, that the laboratory processed patient's samples outside the established temperature range.

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 Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on January 19,2024, at 2: 00PM it was determined that the laboratory director did not assure that the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when the laboratory processed and reported 942 out of 1052 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.
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 Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on January 19,2024, at 2: 00PM, it was determined that the general supervisor did not assure that the manufacturer's instructions were followed by the testing personnel regarding to temperature range for Mycoplasma pneumoniae test. Refer to D5413.