Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2306304	04/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Antillanos,Llc	Carr 860, Esq Ave A,Local 9, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clnico Antillanos, LLC on April 17, 2026. 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 April 17, 2026.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 manufacturer's instructions, Mycoplasma pneumoniae testing records review (years 2025 - 2026), and technical consultant interview on April 17, 2026, at 9:40 a.m., the laboratory failed to follow the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae testing when processed and reported 21 out of 90 patient specimens between July 1, 2025 to April 14, 2026. The findings include: 1. The laboratory used the ImmunoCard Mycoplasma Test Kit to perform qualitative testing for Mycoplasma pneumoniae. 2. On April 17, 2026, at 9:55 a.m., review of the manufacturer's instructions showed the Mycoplasma pneumoniae test procedure had to be performed within a temperature range of 22C to 25C. 3. On April 17, 2026, at 10: 00 a.m., review of the Mycoplasma pneumoniae testing records showed the laboratory

	processed and reported 21 out of 90 patient specimens for Mycoplasma pneumoniae at temperatures of 20.1C to 21.8C, between July 1, 2025, to April 14, 2026. 4. On April 17, 2026, at 10:06 a.m., the technical consultant confirmed that the laboratory processed patient specimens outside the manufacturer's established temperature range.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (year 2025-2026), and technical consultant interview on April 17, 2026, at 11:30 a.m., the laboratory director failed to ensure that the technical consultant monitored compliance with the manufacturer's established temperature requirements for Mycoplasma pneumoniae testing. Refer to D6042.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (year 2025-2026), and technical consultant interview on April 17, 2026, at 11:30 a.m., the technical consultant failed to ensure compliance with the manufacturer's established temperature range for Mycoplasma pneumoniae testing when she processed and reported 21 of 90 patient specimens at temperatures below the required range between July 1, 2025, and April 14, 2026. Refer to D5413.