

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1069513	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Laboratorio Clinico Cuba	Street Address, City, State Carr Pr-125 Km 5 Hm 2 Calle Barbosa 326, Moca, 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 the Laboratorio Clinico Cuba on January 14, 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 January 14, 2026.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the ImmunoCard Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records (year 2025), and interview with the general supervisor on January 14, 2026, at 11:15 a.m., the laboratory failed to follow the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae testing when the laboratory processed and reported 60 of 394 patient specimens outside the manufacturer's required temperature range from January 2, 2025, through December 31, 2025. Findings include: 1. The laboratory used the ImmunoCard Mycoplasma pneumoniae qualitative test to perform Mycoplasma pneumoniae testing. 2. Review of the manufacturer's instructions established a required temperature range of 22C to 25C for test procedures. 3. Review</p>

of Mycoplasma pneumoniae testing records showed that from January 2, 2025, through December 31, 2025, the laboratory processed and reported 60 of 394 patient specimens at a temperature of 21C, which was below the manufacturer's required temperature range. 4. During interview on January 14, 2026, at 11:15 a.m., the general supervisor confirmed that the laboratory processed patient specimens outside the manufacturer's established temperature range.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(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 review of the Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records (year 2025), and interview with the general supervisor on January 14, 2026, at 12:00 p.m., the laboratory director failed to ensure that the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae testing were followed by the general supervisor, the laboratory processed and reported 60 of 394 patient specimens outside the manufacturer's required temperature range. 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 review of the Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records (year 2025), and interview with the laboratory general supervisor on January 14, 2026, at 12:00 p.m., the laboratory general supervisor failed to ensure that the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae testing were followed by testing personnel. Refer to D5413.