Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0907747	03/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Las Mercedes	Carr 2 Km 76-8 Bo Cocos, Quebradillas, 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 Clnico Las Mercedes, on March 20, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on March 20, 2026, the laboratory was found out of compliance with the following conditions: 42 CFR 493.801 Condition: Enrollment and testing of samples. 42 CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reports (CASPER) 0155D, Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 -2026), patient census report for Iron binding capacity, total (TIBC) testing, and general supervisor interview on March 20, 2026, at 9:45 a.m., the laboratory failed to enroll in a Department of Health and Human Services (HHS)-approved Proficiency Testing (PT) Program for the TIBC test, when processed and reported 172 out of 172 patient TIBC tests from January 1, 2025, through March 19, 2026. The findings include: 1. On March 20, 2026, at 9:45 a.m., review of the CASPER Report 0155D and PRPTSP scores showed no proficiency testing results for

	the TIBC test from January 1, 2025, through March 19, 2026. 2. On March 20, 2026, at 10:00 a.m., review of the patient census report for the TIBC testing showed that the laboratory processed and reported 172 out of 172 patient TIBC tests from January 1, 2025, through March 19, 2026. 3. On March 20, 2026, at 10:15 a.m., the general supervisor interview confirmed that the laboratory failed to enroll in an HHS-approved PT Program for the TIBC test.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory schedule for personnel competence, personnel records review (years 2025 - 2026), and laboratory technical supervisor interview on March 20, 2026, at 9:00 a.m., the laboratory failed to follow the established schedule for competency evaluation for the laboratory technical supervisor (MT#3, Form CMS-209). The findings include: 1. The laboratory schedule for personnel competence showed that competency evaluations were performed annually. 2. Review of the personnel records for the laboratory technical supervisor showed the last competency evaluation was performed in January 2024. 3. On March 20, 2026, at 9:30 a.m., the laboratory technical supervisor interview confirmed the last competency evaluation was performed in January 2024.
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 (year 2025), and general supervisor interview on March 20, 2026, at 12:15 p.m., the laboratory failed to follow the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae when processed and reported 16 out of 1,064 patient specimens between April 21, 2025, and April 23, 2025. The findings include: 1. The laboratory used the ImmunoCard Mycoplasma Test Kit to perform qualitative testing for Mycoplasma pneumoniae. 2. On March 20, 2026, at 12:20 p.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 March 20, 2026, at 12:25 p.m., review of the Mycoplasma pneumoniae testing records showed the laboratory processed and reported 16 out of 1,064 patient specimens for Mycoplasma

	pneumoniae at 21.0C between April 21, 2025, and April 23, 2025. 4. On March 20, 2026, at 12:30 p.m., the general supervisor interview confirmed that the laboratory processed patient specimens outside the manufacturer's established temperature range.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reports (CASPER) 0155D, Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), patient census report for Iron binding capacity, total (TIBC) testing, Mycoplasma pneumoniae quality control (year 2025) and general supervisor interview on March 20, 2026, at 1:30 p.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory's Proficiency Testing Program and quality control. Refer to D6088 and D6093.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reports (CASPER) 0155D, Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), patient census report for Iron binding capacity, total (TIBC) testing, and general supervisor interview on March 20, 2026, at 1:30 p.m., the laboratory director failed to ensure that the laboratory technical supervisor was enrolled in an HHS-approved Proficiency Testing Program for the TIBC test. Refer to D6116.
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 ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (year 2025), and general supervisor interview on March 20, 2026, at 1:35 p.m., the laboratory director failed to ensure that the general supervisor monitored compliance with the analytic system requirements for Mycoplasma pneumoniae patient testing. Refer to D5413 and D6144.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reports (CASPER) 0155D, Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 -2026), patient census report for Iron binding capacity, total (TIBC) testing, and general supervisor interview on March 20, 2026, at 1:30 p.m., the laboratory technical supervisor failed to enroll the laboratory in an HHS-approved Proficiency Testing Program for the TIBC test, when the laboratory processed and reported 172 out of 172 patient TIBC tests from January 1, 2025, through March 19, 2026.
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 ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (year 2025), and general supervisor interview on March 20, 2026, at 1:35 p.m., the general supervisor failed to ensure that the testing personnel followed the manufacturer's instructions for the established temperature range for Mycoplasma pneumoniae testing. Refer to D5413 and D6175.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) (b) Each individual performing high complexity testing must-- (b)(1) Follow the laboratorys procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; This STANDARD is not met as evidenced by: Based on ImmunoCard Mycoplasma manufacturer's instructions, Mycoplasma pneumoniae testing records review (year 2025), and general supervisor interview on March 20, 2026, at 1:35 p.m., the testing personnel failed to follow the manufacturer's instructions regarding the established temperature range for Mycoplasma pneumoniae testing, when processed 16 out of 1,064 patient specimens for Mycoplasma pneumoniae. Refer to D5413.