Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0657993	03/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rodriguez	Calle Gonzalo Marin #111 Suite #1, Arecibo, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2025), hematology Proficiency Testing (PT) scores (year 2025) and laboratory director interview on March 6, 2026 at 8:30 a.m., the laboratory failed to evaluate the accuracy of testing in the hematology specialty when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 1095 patient samples from June 2025 through March 6, 2026. The findings include: 1. PRPTSP were reviewed from February 2024 through December 2025. 2. Review of the hematology PT scores for the third testing event in 2025 showed that the PT provider assigned an artificial score of 100 percent. The results were not evaluated. 3. During interview On March 6, 2026, at 8: 40 a.m., with the laboratory director, the accuracy of the excused hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The laboratory director stated that no procedure for accuracy evaluation was performed. 4. The laboratory director on March 6, 2026, at 8:40 a.m, also stated that no written procedure was developed by the laboratory to evaluated the accuracy of test not evaluated by the PT provider. 5. From June 2025 through March 6, 2026, the laboratory processed and reported 1095 patient samples.
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 Mycoplasma Pneumoniae IgM test quality control records review (year 2024-2026), manufacturer's instructions review, and laboratory directer interview on March 6, 2026 at 10:30 A.M., the laboratory failed to monitor and document the room temperature, when 36 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test from June 2, 2025 to August 22, 2025. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. On March 6, 2026 at 10:30 A.M. the manufacturer's instructions were reviewed, and it establishes to perform the test procedures at room temperature from 22 to 25 C. 3. On March 6, 2026 at 10:40 A.M, review of the Mycoplasma pneumoniae IgM quality control records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma pneumoniae IgM from June 2, 2025 to August 22, 2025. 4. The laboratory director confirmed on March 6, 2026 at 10:40 A.M, that the laboratory did not monitor nor document the room temperature when they processed the patient's specimens for Mycoplasma pneumoniae IgM test. 5. The laboratory processed and reported 36 patient samples for Mycoplasma pneumoniae IgM test from June 2, 2025 to August 22, 2025.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the Urinalysis quality control record and interview with the laboratory director interview on March 6, 2026 at 10:08 A.M, the laboratory did not meet the quality control requirements for manual microscopis urinalysis examination sisnce January 2024. The finding include : 1. The urinalysis quality control records were reviewed on March 6, 2026 at 10:08 AM. The laboratory did not have established quality control requirements for manual microscopis urinalysis examination. 2. The quality control records showed that the laboratory did not performed the negative control material for the microscopic urinalysis control material since January 2024. 3. The laboratory director confirmed on March 6, 2026 at 10:20 AM; that the laboratory did not performed the negative quality control records for manual microscopic urinalysis examinations
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff

	to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2025), hematology Proficiency Testing (PT) scores (year 2025) and laboratory director interview on March 6, 2026 at 8:30 a.m., the laboratory director failed to evaluate the accuracy of testing in the hematology specialty when the laboratory received an artificially score of 100 percent from the PT provider.
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 urinalysis quality control records review (2024-2025) , mycoplasma manufacturer's instructions review, and laboratory director interview on March 6, 2026 at 11:30 A.M., it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the quality control requirements. Refer to D5413 and D5449.