Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658300	09/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Dr Cordova	1055 Brumbaugh St, Rio Piedras, 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 Dr Cordova on September 4, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on September 4, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 Condition: General immunology 42 CFR 493.1210 Condition: Routine chemistry 42 CFR 493.1250 Condition: Analytic Systems 42 CFR 493.1441 Condition: Laboratories performing high complexity testing; laboratory director In addition, the laboratory was found out of compliance with the following standard level deficiencies found during the recertification CLIA survey on September 4, 2025.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (years 2024-2025) and interview with the laboratory technical supervisor on September 4, 2025, at 11:52 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. Refer to: D5449 and D5413.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.

	1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on routine chemistry quality control records review (years 2024-2025) and interview with the laboratory technical supervisor on September 4, 2025, at 10:25 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry test. Refer to D5439.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on quality control records review, manufacturer's instructions review, and laboratory technical supervisor interview on September 4, 2025 at 12:325 PM, it was determined that the laboratory failed to follow the analytic system requirements. Refer to 5014, D5016 and D5024
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, manufacturer's instructions review, and laboratory supervisor interview on September 4, 2025 at 11:52 AM, it was determined that the laboratory failed to monitor and document the room temperature, when 23 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. On September 4, 2025 at 11:45 AM the manufacturer's instructions were reviewed, and it establishes to perform the test procedures at room temperature from 22 to 25 C. 3. On September 4, 2025 at 11:42 AM, 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 in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024. 4. The laboratory supervisor confirmed on September 4, 2025 at 11:42 AM, that the laboratory did not monitor nor document the room temperature when they processed the patient's specimens for Mycoplasma pneumoniae IgM test. The laboratory processed and reported 23 patient samples for Mycoplasma pneumoniae IgM in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (years 2024-2025) and interview with the laboratory director on September 4, 2025, at 10:25 AM, it was determined that the laboratory did not perform, at least every six months, the calibration verification procedures for sodium (Na+), potassium (K+), and chloride (Cl-) tests, when processed and reported 2,716 out of 2,716 electrolytes patient's test from August 2024, to August 2025. The findings include: 1. The laboratory used the Ortho Vitros 250 Chemistry Analyzer to perform Na+, K+, and Cl- tests. (Reviewed on September 4, 2025, at 10:07 AM) 2. The laboratory performed Na+, K+, and Cl- calibration verification procedures in February 2024 and August 2025. (Reviewed on September 4, 2025, at 10:10 AM) 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform Na+, K+, and Cl- calibration verification procedure in August 2024 and February 2025. (Reviewed on September 4, 2025, at 10:10 AM) 4. The laboratory supervisor confirmed on September 4, 2025, at 10:25 AM, that the laboratory failed to perform, at least every 6 months, the calibration verification procedures for Na+, K+, and Cl- tests. The laboratory processed and reported 2,716 out of 2,716 electrolytes patient's test from August 2024, to August 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 the Mycoplasma pneumoniae IgM quality control records reviewed, manufacturer instructions and laboratory supervisor interview on September 4, 2025 at 11:52 A.M., it was determined that the laboratory did not perform the external negative and positive control material in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024. The findings include: 1. Review of the Mycoplasma pneumoniae IgM quality control records on September 4, 2025 at 11:45 A.M, showed that the laboratory did not perform the external negative and positive control material each day of patient testing. 3. The laboratory supervisor confirmed on September 4, 2025 at 11:52 A.M., that the laboratory failed to perform the negative and positive external control material in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024. The laboratory processed and reported 23 patient samples.
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 Routine chemistry, Hematology, Mycoplasma Pneumoniae IgM quality control records, manufacturer's instructions, and interview with the laboratory supervisor on September 4, 2025 at 12:30 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093 and D6095.
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 Routine chemistry, Hematology, Mycoplasma Pneumoniae IgM quality control records, manufacturer's instructions, and interview with the laboratory supervisor on September 4, 2025 at 12:30 PM, it was determined that the laboratory director failed to fulfill to ensure the compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5413 and D5449.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical

	performance for each test system; This STANDARD is not met as evidenced by: Based on Mycoplasma Pneumoniae IgM test quality control records review, manufacturer's instructions review, and laboratory supervisor interview on September 4, 2025 at 11:52 AM, it was determined that the laboratory director failed to ensure that the established quality control program was followed and failed to ensure that the laboratory monitored and documented the room temperature, when 23 patient specimens were processed and reported for Mycoplasma pneumoniae IgM test in the following days: June 18, 2024; June 21, 2024; June 24, 2024; June 25, 2024; June 28, 2024; July 1, 2024; July 2, 2024; July 11, 2024; July 12, 2024; July 15, 2024. Refer to D5413 and D5449.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of the hematology DxH 520 instrument performance verification results and laboratory technical supervisor interview on September 4, 2025 at 11:18 AM, it was determined that the laboratory technical supervisor failed to evaluate the instrument's obtained results. The laboratory processed and reported 1,698 since the performance verification on December 15, 2023 The findings include: 1. On September 4, 2025 at 11:02 AM; review of the Beckman Coulter Installation Work Order Report showed, that the laboratory installed the DxH 520 hematology system on December 15, 2023. 2. On September 4, 2025 at 11:02 AM, review of the DxH 520 instrument performance verification results did not reflect the evaluation and signature of the laboratory technical supervisor prior to begin to test Complete Blood Count (CBC) patient samples. 3. The laboratory technical supervisor confirmed on September 4, 2025 at 11:02 AM, that the laboratory director did not evaluate and sign the performance verification of the DxH 520 hematology system. 4. The laboratory processed and reported 1,698 CBC tests on the DxH 520 hematology system from December 15, 2023 to September 4, 2025.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(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: A. Based on the Mycoplasma pneumoniae IgM quality control records reviewed, manufacturer instructions and laboratory technical supervisor interview on September 4, 2025 at 11:52 A.M., it was determined that the laboratory technical supervisor did

	not ensure that the quality control establish were followed. Refer to D5413 and D5449. B. Based on Routine chemistry quality control records review and interview with the laboratory technical supervisor on September 4, 2025 at 12:25 PM, it was determined that the laboratory technical supervisor failed to ensure that the calibration verification of routine chemistry specialty were followed. Refer to D5439.