Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0901411	03/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Plaza Carolina Inc	Ofc #12 3rd Floor Plaza Carolina Mall, 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 the Laboratorio Clnico Plaza Carolina Inc., on March 27, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on March 27, 2026, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1250 Condition: Analytic Systems 42 CFR 493.1403 Condition: Moderate Complexity Laboratory Director 42 CFR 493.1409 Condition: Technical Consultant-Moderate Complexity
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 personnel records review (years 2025-2026) and laboratory technical consultant interview on March 27, 2026 at 9:45 AM, the laboratory failed to follow the established schedule for competency evaluation for the clinical consultant and technical consultants (#8475 and #8514) who also they perform testing on patient specimen. The finding includes: 1. On March 27, 2026 at 9:40 AM, the laboratory written policies for personnel competency procedures showed that the competency procedures must be performed annually. 2. The laboratory did not perform, as established (annually), the competency evaluation for the technical consultants (#8475 and #8514), clinical consultant during since 2025. 3. During the interview on March 27, 2026 at 9:45 AM, the laboratory technical consultant (#8475) confirmed that the laboratory did not perform the competency evaluations for the following personnel: clinical consultant and technical consultant (#8475 and #8514) who also they perform testing on patient specimen.

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 technical consultant interview on March 27, 2026, at 9:53 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 569 patient samples from June 2025 through March 26, 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 27, 2026, at 9:53 A.M.; with the technical consultant, the accuracy of the excused hematology specialty (Complete Blood Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The technical consultant stated that no procedure for accuracy evaluation was performed. 4. The technical consultant on March 27, 2026, at 9:58 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 26, 2026, the laboratory processed and reported 569 patient samples.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory technical consultant on March 27, 2026 at 10:18 AM; the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2025. The findings include: 1. The QA was requested and review on March 27, 2026 at 10:00 AM. The QA showed that the laboratory did not monitor the following general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2025. 2. The laboratory technical consultant confirmed on March 27, 2026 at 10:18 AM that the laboratory failed to monitor the general laboratory systems practices related to: patient confidentiality, specimen identification and integrity, complaint investigations, communications since January 2025.

D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory technical consultant on March 27, 2026 at 10:18 A.M.; the laboratory failed to monitor the preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2025. The findings include: 1. The QA was requested on March 27, 2026 at 10:00 A.M.; the QA showed that the laboratory did not monitor the following preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2025. 2. The Laboratory technical consultant confirmed on March 27, 2026 at 10:18 A.M.; that the laboratory failed to monitor the preanalytic systems activities related to: test request, specimen submission, handling and referral, since January 2025.
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 the review of the quality assessment, quality control records and interview with the laboratory technical consultant on March 27, 2026 at 1:30 P.M., the laboratory failed to meet the analytic system requirements. Refer to D5445, D5449, D5783, D5793.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

	This STANDARD is not met as evidenced by: Based on the syphilis serology quality control records reviewed, manufacturer instructions and laboratory technical consultant interview on March 27, 2026 at 12:50 P.M., it was determined that the laboratory did not include the reactive; weakly-reactive and non-reactive control material each day of patients testing. The laboratory processed and reported four (4) patients sample from January 2026 to March 2026. The findings include: 1. The manufacturer's instructions were reviewed on March 27, 2026 at 12:46 P.M.; the manufacturer established that the reactive; weakly-reactive and non-reactive control material must be performed every day of patients testing. 2. Review of the syphilis serology quality control records on March 27, 2026 at 12:46 P. M.; showed that the laboratory did not perform the reactive; weakly-reactive and non-reactive control material each day of patient testing. The laboratory processed and reported four (4) patients sample from January 2026 to March 2026. 3. The laboratory technical consultant confirmed on March 27, 2026 at 12:50 P.M., that the laboratory failed to perform the reactive; weakly-reactive and non-reactive control material each day of patients testing. The laboratory processed and reported four (4) patients sample from January 2026 to March 2026.
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: A. Based on review of the Urinalysis quality control record and interview with the laboratory technical consultant interview on March 27, 2026 at 11:34 A.M.; the laboratory did not meet the quality control requirements for manual microscopic urinalysis examination since February 2025. The laboratory processed and reported 664 patient samples. The finding include : 1. The urinalysis quality control records were reviewed on March 27, 2026 at 11:28 A.M., the laboratory had established to performed quality control for manual microscopic urinalysis examinations. 2. The quality control records showed that the laboratory did not performed the negative or positive control material for the microscopic urinalysis control material since February 2025. 3. The laboratory technical consultant confirmed on March 27, 2026 at 11:34 AM; that the laboratory did not performed the quality control for manual microscopic urinalysis examinations. The laboratory processed and reported 664 patient samples. B. Based on the Human Chorionic Gonadotropin (hCG) quality control records review (years 2025-2026), and laboratory technical consultant interview on March 27, 2026 at 12:25 P.M., the laboratory failed to include an external negative and positive control material, each day of patient testing. The laboratory processed and reported three (3) hCG patient samples from January 2026 to March 2026. The findings include: 1. Review of the hCG test quality control records (years 2025-2026), on March 27, 2026 at 12:15 P.M., showed that the laboratory failed to include an external negative and positive control material, each day of patient testing, when the laboratory processed and reported three (3) hCG patient samples from January 2026 to March 2026. 2. The laboratory technical consultant confirmed on March 27, 2026 at 12:25 P.M., that the laboratory failed to perform the external negative and positive control material each day of patient testing. The laboratory processed and reported three (3) hCG patient samples from January 2026 to March 2026. C. Based on the Mycoplasma pneumoniae IgM quality control records review, and technical consultant interview on March 27, 2026 at 1:18 P.M., the laboratory failed to include an external negative and positive control material each day of patient

	testing. The laboratory processed and reported two (2) patient samples from January 2026 to March 2026. The findings include: 1. The laboratory uses the Immuno Card Mycoplasma kit to perform the Mycoplasma pneumoniae IgM tests. 2. Review of the Mycoplasma pneumoniae IgM test quality control records on March 27, 2026 at 1:08 P.M., showed that the laboratory did not perform the external negative and positive control material each day of patient testing, when the laboratory processed and reported two (2) patient samples from January 2026 to March 2026. 3. The laboratory technical consultant confirmed on March 27, 2026 at 1:18 P.M., that the laboratory failed to perform the external negative and positive control material each day of patient testing. The laboratory processed and reported two (2) patient samples from January 2026 to March 2026.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of hematology quality control from years 2025-2026, procedure manual and interview with the laboratory technical consultant on March 27, 2026 at 10:54 AM., the laboratory did not evaluate nor take any corrective actions when the control material fail to meet the laboratory's criteria for acceptability for platelet count. The laboratory processed and reported 18 out of 138 patient samples in the following days: July 29, 2025, August 11, 2025, August 12, 2025 and August 21, 2025. The findings include: 1. The laboratory performed the platelet count in the Act-5 diff by Beckman coulter during year 2025. 2. The quality control records were reviewed on March 27, 2026 at 10:31 A.M., from January 2025 to March 2026. 3. The laboratory procedure manual showed that, if more than one (1) value are below the three (3) standard deviation (3SD), the laboratory must take and document a corrective action. 4. Review of quality control graphs showed that the laboratory failed to take corrective action when the control material for platelet count (high level and normal level) exceeded the laboratory limits below the 3SD more than 4 plots. 5. The laboratory technical consultant confirmed on March 27, 2026 at 10:54 A.M., that no corrective action were taken. The laboratory processed and reported 18 out of 138 patient samples in the following days: July 29, 2025, August 11, 2025, August 12, 2025 and August 21, 2025.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory technical consultant on March 27, 2026 at 10:18 AM; the laboratory failed to monitor the analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2025. The findings include: 1. The QA was requested and review on March 27, 2026 at 10:00 AM. The QA showed that the laboratory did not monitor the following analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2025. 2. The laboratory technical consultant confirmed on March 27, 2026 at 10:18 AM, that the laboratory failed to monitor the analytic systems activities related to: test procedures, test systems, equipment, instruments, reagents, materials, and supplies for accuracy and reliability, specimen and reagent storage conditions, equipment, instrument, test, systems maintenance and function checks, control procedures, comparison of test results; corrective actions and test records, since January 2025.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Quality Assessment (QA) records and interview with the laboratory technical supervisor on March 27, 2026 at 10:18 A.M.; the laboratory failed to monitor the postanalytic systems activities related to: test report, turn-around time, since January 2025. The findings include: 1. The QA was requested and review on March 27, 2026 at 10:00 A.M.; the QA showed that the laboratory did not monitor the following postanalytic systems activities related to: test report, turn-around time, since January 2025. 2. The laboratory technical consultant confirmed on March 27, 2026 at 10:18 A.M.; that the laboratory failed to monitor the postanalytic systems activities related to: test report, turn-around time, since January 2025.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on Puerto Rico proficiency program, quality control records review, quality assessment review, manufacturer's instructions review, and laboratory technical

	consultant interview on March 27, 2026 at 1:28 P.M., the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the preanalytic, analytic and postanalytic requirements. Refer to D5400 and D6007.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on Puerto Rico proficiency program, quality control records review, quality assessment review, manufacturer's instructions review, and laboratory technical consultant interview on March 27, 2026 at 1:28 P.M., the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the preanalytic, analytic and postanalytic requirements. Refer to D5209, D5215, D5293, D5393, D5445, D5449, D5783 and D5793.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel competency, quality control records, Puerto Rico proficiency program and interview with the technical consultant on March 27, 2026 at 1:28 P.M., the technical consultant did not fulfill his responsibilities with the laboratory. Refer to D6046, D6049.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on personnel records review (years 2025-2026) and laboratory technical consultant interview on March 27, 2026 at 9:45 AM, the laboratory technical consultant failed to follow the established schedule for competency evaluation for the technical consultants (#8475 and #8514, also they perform testing on patient specimens), and the clinical consultant. Refer to D5209.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)

	(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of patinet worksheets records, quality control records, proficiency testing records and interview with the technical consultant on March 27, 2026 at 1:28 P.M., the technical consultant failed to review and ensure that the establishing parameter for acceptable levels of analytic requirements were follow. refer to D5215, D5445, D5449, D5783.