Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669530	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Los Robles	#308 Americo Miranda Ave, 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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clnico Los Robles on April 9, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. During a recertification survey on April 9, 2026, the laboratory was found out of compliance with the following conditions: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), Certification and Survey Provider Enhanced Reports (CASPER) 0155D, and interview with the laboratory director on April 9, 2026, at 11:15 a.m., the laboratory failed to take and document corrective action when it obtained an unsatisfactory score in the subspecialty of routine chemistry for the analyte alkaline phosphatase (ALP) in the third proficiency testing event of 2025. The laboratory processed and reported 83 out of 83 patient test results for ALP from June 2025 through October 2025. The findings included: 1. The PRPTSP scores and CASPER Report 0155D were reviewed for the period of January 2025 through December 2025. 2. Review of PRPTSP scores and CASPER Report 0155D showed that the laboratory obtained an unsatisfactory score of 20 % (percent) for the ALP analyte in the third

	proficiency testing event of 2025 and failed to take or document any remedial or corrective action. 3. The laboratory processed and reported 83 out of 83 patient test results for ALP from June 2025 through October 2025. 4. On April 9, 2026, at 11:30 a. m., the laboratory director confirmed during interview that the laboratory failed to take and document corrective action when it obtained an unsatisfactory ALP proficiency testing score.
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 the laboratory schedule for personnel competency, personnel records review (years 2024 - 2026), and laboratory director interview on April 9, 2026, at 10:12 a.m., the laboratory failed to follow the established schedule for competency evaluation of the laboratory clinical consultant. The findings include: 1. The laboratory schedule for personnel competency showed that competency evaluations were performed annually. 2. Review of the personnel records for the laboratory clinical consultant showed that the last competency evaluation was performed in February 2023. 3. The laboratory failed to perform the annual competency evaluation for the laboratory clinical consultant during years 2024 through 2026. 4. On April 9, 2026, at 10:17 a.m., the laboratory director confirmed during interview that the last competency evaluation for the laboratory clinical consultant was performed in February 2023.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of syphilis serology quality control records, patient testing worksheet records (year 2025), the manufacturer's instructions, and laboratory director interview on April 9, 2026, at 2:15 p.m., that the laboratory failed to follow the manufacturer's instructions regarding cleaning of the needle assembly for syphilis serology testing. The laboratory processed and reported 26 out of 26 Rapid Plasma Reagin (RPR) patient specimens from February 10, 2025, through December 22, 2025. The findings include: 1. The laboratory used the ASI's reagent kit to perform syphilis serology testing. 2. On April 9 ,2026 at 2:17 p.m., review of the ASI's manufacturer's instructions showed the needle assembly had to be thoroughly washed in distilled or deionized water and air dried after each shift. 3. On April 9, 2026, at 2:15 p.m., review of syphilis serology quality control and patient testing worksheet records showed that the laboratory did not perform or document the needle wash procedure after each shift, when processed and reported 26 out of 26 RPR patient specimens from February 10, 2025, through December 22, 2025. 4.On April 9,2026, at 2:20 p.m., the laboratory director confirmed during interview that the laboratory did not follow

	the manufacturer's instructions regarding cleaning of the needle assembly after each shift.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration records (years 2024 -2025), Medonic M-series manufacturer's instructions review, and laboratory director interview on April 9, 2026, at 1:43 p.m., the laboratory failed to perform calibration procedures at the frequency established by the manufacturer, at least every six (6) months, for hematology testing performed on the Medonic M-Series hematology analyzer. The laboratory processed and reported 339 out of 339 complete blood count (CBC) patient specimens during the periods of December 2024 through June 2025 and December 2025 through April 8, 2026. The findings include: 1. The laboratory used the Medonic M-Series hematology analyzer to perform CBC testing. 2. Review of the Medonic M-series manufacturer's instructions showed the instrument required calibration at least every six months. 3. Review of hematology calibration records showed the laboratory did not perform calibration procedures for the Medonic M-Series hematology analyzer at least every six months. The laboratory performed calibration procedures in June 2024 and June 2025 and did not perform the required calibration procedures in December 2024 and December 2025. 4. The laboratory processed and reported 339 out of 339 CBC patient specimens during the periods of December 2024 through June 2025 and December 2025 through April 8, 2026, without performing the required calibration procedure. 5. On April 9, 2026, at 1:51 p.m., the laboratory director confirmed during interview that the laboratory did not perform calibration procedures for the Medonic M-Series hematology analyzer at least every six months.
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 a review of routine chemistry calibration verification records (years 2024-2025), the routine chemistry calibration verification procedure, and interview with the laboratory director on April 9, 2026, at 1:00 p.m., the laboratory failed to perform calibration verification at least every six months for routine chemistry testing performed on the RX Daytona Chemistry Analyzer. The laboratory processed and reported routine chemistry test results for 911 out of 911 patients from June 2024 through August 2025. The findings included: 1.The laboratory used the RX Daytona Chemistry Analyzer to perform routine chemistry testing. 2. On April 9, 2026, at 1:00 p.m., the laboratory director stated that the routine chemistry calibration verification procedure required calibration verification for routine chemistry testing on the RX Daytona Chemistry Analyzer to be performed at least every six months. 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform calibration verification at least every six months. The last calibration verification was performed in December 2023. 4. The laboratory processed and reported routine chemistry test results for 911 out of 911 patients from June 2024 through August 2025. 5. On April 9, 2026, at 1:26 p.m., the laboratory director confirmed during interview that the laboratory did not perform calibration verification from June 2024 through August 2025.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records (years 2025 - 2026) for the Medonic M-Series analyzer and interview with the laboratory director on April 9, 2026, 2026, at 1:35 p.m., the laboratory failed to verify the manufacturer's stated values for Boule Con-Diff Tri-Level hematology control materials before it placed new control lots into routine use. The laboratory processed and reported 309 of 309 Complete blood count (CBC) patient specimens from June 5, 2025, through April 8, 2026. The findings included: 1. Review of hematology quality control records showed the laboratory used Boule Con- Diff Tri-Level control materials to monitor CBC testing on the Medonic M-Series hematology analyzer. 2. Review of QC records

	showed the laboratory placed the following lots of Boule Con-Diff Tri-Level hematology control materials into routine use without verifying the manufacturer's stated values: a. Control Lot number: 2250461 (Low control), 2250462 (Normal control) and 2250463 (High control) Used dates: June 5, 2025, through August 29, 2025. Patient specimens processed and reported: 124 b. Control Lot number: 2250761 (Low control), 2250762 (Normal control) and 2250763 (High control) Used dates: August 30, 2025, through November 24, 2025. Patient specimens processed and reported: 132 c. Control Lot number: 2251061 (Low control), 2251062 (Normal control) and 2251063 (High control) Used dates: December 1, 2025, through January 8, 2026. Patient specimens processed and reported: 38 d. Control Lot number: 2260161 (Low control), 2260162 (Normal control) and 2260163 (High control) Used dates: March 20, 2026, through April 8, 2026. Patient specimens processed and reported: 15 3. The laboratory processed and reported 309 of 309 CBC patient specimens from June 5, 2025, through April 8, 2026. 4. On April 9, 2026, at 2:10 p. m., the laboratory director confirmed during interview that the laboratory placed the Boule Con-Diff Tri-Level hematology control materials into routine use without first verifying the manufacturer's stated values.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the Quality Assessment (QA) program (years 2024-2025) and interview with the laboratory director on April 9, 2026, at 11:35 a.m., the laboratory failed to follow its established QA program to monitor and evaluate the laboratory's turn-around times (TAT) as part of the postanalytical system. The findings included: 1. On April 9, 2026, at 11:35 a.m., review of the laboratory's QA program showed that the laboratory required annual evaluation of TAT. 2. Review of QA records showed that the laboratory last evaluated TAT in December 2023 and did not perform TAT evaluations for the years 2024 and 2025. 3. On April 9, 2026, at 2:50 p.m., the laboratory director confirmed during interview that the laboratory did not perform TAT evaluations during the years 2024 and 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 review of Quality Control (QC) records (years 2024-2026) records, review of the Quality Assessment (QA) program (years 2024-2025), and laboratory director interview on April 9, 2026, at 3:10 p.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory's QC and QA requirements for routine chemistry, hematology, and syphilis serology (RPR), and with the laboratory's QA requirements for TAT. Refer to D6020.

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 (PRPTSP) scores (year 2025), the CASPER Report 0155D, and laboratory director interview on April 9, 2026, at 3:08 p. m., the laboratory director failed to take corrective action when the laboratory obtained an unsatisfactory score for the alkaline phosphatase (ALP) analyte in the third proficiency testing event of 2025. Refer to D2094.
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 review of Quality Control (QC) records (years 2024-2026) records, review of the Quality Assessment (QA) program (years 2024-2025), and laboratory director interview on April 9, 2026, at 3:10 p.m., the laboratory director failed to ensure compliance with the laboratory's QC requirements for routine chemistry, hematology and syphilis serology (RPR), and with the laboratory's QA requirements (TAT). Refer to D5411, D5437, D5439, D5469 and D5891.