Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2263629	06/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clinica Todo Salud - Laboratorio Clinico	Parque Industrial L-238-0-61, Carretera Pr-725,, Aibonito, 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 Clnica Todo Salud - Laboratorio Clnico on June 24, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on June 24, 2026.
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 2025 - 2026), Certification and Survey Provider Enhanced Reports (CASPER Report 0155D) scores, hematology Proficiency Testing (PT) scores (year 2025) and laboratory general supervisor interview on June 24, 2026, at 9:55 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 2,773 patient samples from June 2025 through Febraru 28, 2026. The findings include: 1. The CASPER Report 0155D scores were review on June 8, 2026 at 8:00 AM, and show that the laboratory received 100 percent score in the third event of hematology in the year 2025. 2. PRPTSP were reviewed from February 2025 through June 2026. 3. 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. 4. During interview on June 24, 2026, at 9:50 A.M.; with the laboratory general supervisor, the accuracy of the excused hematology specialty (Complete Blood Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The laboratory general supervisorr stated that no procedure for accuracy evaluation was performed. 5. The laboratory general supervisor also stated on June 24, 2026, at 9:55 A.M.; that no written procedure was developed by the laboratory to evaluated the accuracy of test not evaluated by the PT provider. 6. From June 2025 through February 28, 2026, the laboratory processed and reported 2,773 patient samples.
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 2025-2026) and interview with the laboratory general supervisor on June 24, 2026, at 11:00 AM, it was determined that the laboratory did not perform, at least every six months, the calibration verification procedures for Troponiin I tests, when processed and reported one hundred twenty eighty nine (189) Troponiin I patient's test from September 2026 to June 2026. The findings include: 1. The laboratory used the Ramp 200 Chemistry Analyzer to perform Troponin I tests. (Reviewed on June 24, 2026 at 10:50 AM) 2. The laboratory performed validatiioin procedures for Troponin I in August 2025. (Reviewed on June 24, 2026 at 10:52 AM) 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform Troponin I calibration verification procedure in February 2026. (Reviewed on June 24, 2026 at 10:58 AM) 4. The laboratory processed and reported one hundred twenty three (123) Troponin I patient's test from February 1, 2026 to June 23, 2026. (Reviewed on June 24, 2026 at 11:00 AM) 5. The laboratory general supervisor confirmed on June 24, 2026 at 11:00 AM, that the laboratory failed to perform, at least every 6 months, the calibration verification procedures for Troponin I tests.
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 lack of routine chemistry Troponin I tests Levey - Jennings control chart (years 2025-2026) and interview with the laboratory general supervisor on June 24, 2026 at 11:00 AM., it was found that the laboratory did not evaluate nor define the statistical values of any of the all the lot numbers of the commercial control material used by the RAMP 200 Chemistry Analyzer when processed and reported one hundred eitghty nine (189) Troponin I tests from September 2026 to June 23, 2026. The findings include: 1. The laboratory used the Ramp 200 Chemistry Analyzer to perform Troponin I tests (Reviewed on June 24, 2026 at 10:50 AM) 2. The laboratory did not have any statistical data (Levey - Jennings control chart , control value means and limits) used from September 2026 to June 23, 2026. (Reviewed on June 24, 2026 at 10:52 AM) 3. The laboratory general supervisor stated on June 24, 2026 at 11:00 AM. for the years 2025 and 2026 the laboratory did not have available the evaluations of the control results to detect any outliers, shifts or trends in control values. (Reviewed on June 24, 2026 at 10:56 AM) 4. The records showed that the laboratory processed and reported one hundred eighty nine (189) Troponin I tests from September 2026 to June 23, 2026. (Reviewed on June 24, 2026 at 11:00 AM)
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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) (year 2025 and 2026), Certification and Survey Provider Enhanced Reports (CASPER Report 0155D), hematology proficiency tests laboratory records and interview with the laboratory general supervisor on June 24, 2026 at 9:50 AM, the laboratory director failed to verify the accuracy of the hematology proficiency test when the laboratory obtained an artificial score. Refer to D5215.
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 calibration verification records review (years 2025-2026), quality control records review (years 2025-2026)and interview with the laboratory general supervisor on June 24, 2026, at 11:00 AM, the laboratory director failed to

	fulfill her responsibilities and duties to ensure compliance with the quality control requirements. Refer to D5439 and D5483.