Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0677191	06/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Alhambra	Calle Comercio #104, Juana Diaz, 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 Alhambra on June 9, 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 9, 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 Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2026), Hematology Proficiency Testing (PT) scores (year 2025), and interview with the Technical Supervisor (TS) on June 9, 2026, at 10:17 a.m., the laboratory failed to evaluate the accuracy of patient testing for the Hematology specialty (Complete Blood Count (CBC) and White Blood Cell (WBC) 5-Parameter testing), when the PT provider assigned an artificial score of 100 percent. The laboratory processed and reported 2,392 out of 2,392 patient test results from March 2025 through November 2025. The findings include: 1. CASPER and PRPTSP (Hematology PT) scores were reviewed from June 2024 through March 2026. 2. Review of the Hematology PT scores for the second testing event in 2025 showed that the PT provider assigned an artificial score of 100 percent in WBC 5-Parameter; and the third testing event in 2025 showed that the PT provider assigned an artificial score

	of 100 percent for CBC and WBC 5-Parameter. The results were not evaluated. 3. During interview on June 9, 2026, at 10:25 a.m., with the TS, the evaluation of the accuracy of the excused Hematology specialty (Complete Blood Count (CBC) and White Blood Cell (WBC) 5- Parameter) was required. 4. The laboratory processed and reported 2,392 out of 2,392 patient samples from March 2025 through November 2025. 5. The TS stated on June 9, 2026, at 10:28 a.m., that the laboratory did not evaluate the accuracy of the Hematology specialty test.
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 review of Bacteriology quality control (QC) records (years 2025-2026), the laboratory's Individualized Quality Control Plan (IQCP), and laboratory Technical Supervisor (TS) interview on June 9, 2026, at 12:15 p.m., the laboratory failed to implemented a Quality Control Plan (QCP) for antimicrobial susceptibility using a new testing panel prior to reporting patient results. The laboratory processed and reported 101 out of 101 antimicrobial susceptibility test results from July 23, 2025, to June 8, 2026. The findings include: 1. The laboratory used the VITEK 2 system to perform organism identification and antimicrobial susceptibility testing. The laboratory revised the IQCP in December 2024. 2. On June 9, 2026, at 12:15 p.m., review of the QC records showed that the laboratory implemented a new antimicrobial susceptibility testing (AST) panel, XN-806, on July 23, 2025. 3. Review of the QC record and IQCP showed that the laboratory did not implemented a QCP for the new susceptibility testing panel XN-806, however, the QC records ahowed that control procedures were perform on a weekly basis. 4. The laboratory processed and reported 101 out of 101 patient samples with the AST panel XN-806 from July 23, 2025, to June 8, 2026. 5. During interview on June 9, 2026, 2025, at 12:58 p.m., the TS confirmed that the laboratory did not evaluate the QCP for the new testing panel.
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 Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024 - 2026), Hematology proficiency testing (PT) scores (year 2025), and interview

	with the Technical Supervisor (TS) on June 9, 2026, at 10:30 a.m., the laboratory director failed to ensure that the TS evaluated and documented the accuracy of Hematology testing results that were not evaluated by the PT provider. 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 review of Bacteriology quality control (QC) records (years 2025-2026), the laboratory's Quality Control Plan (QCP), and laboratory Technical Supervisor (TS) interview on June 9, 2026, at 3:00 p.m., the laboratory director failed to ensure that the TS established and maintained the QCP, to assure the quality of Bacteriology testing. Refer to D6117.
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: Based on review of Bacteriology Quality Control (QC) records (years 2025-2026), the Quality Control Plan (IQCP), and laboratory Technical Supervisor (TS) interview on June 9, 2026, at 3:00 p.m., the TS failed to evaluate or revise the QCP for the new testing panel prior to patient testing. Refer to D5445.