Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1079403	06/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rq	Carr Pr 112 Km 5 Hm 3 Bo Arenales Altos, Isabela, 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 RQ on June 11, 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 11, 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 2025 - 2026), hematology Proficiency Testing (PT) scores (year 2025), and interview with the testing personnel (TP) on June 11, 2026, at 9:21 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-Parameters testing), when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 1,845 out of 1,845 patient samples from June 2025 through November 2025. The findings include: 1. CASPER and PRPTSP (hematology PT) scores were reviewed from February 2025 through March 2026. 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 for CBC and WBC 5-Parameters testing. The results were not evaluated. 3. During interview on June 11,2026, at 9:26 a.m.,

	with the TP, the accuracy of the excused hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The LD stated that the laboratory did not evaluate the accuracy of the hematology specialty test. 4. The laboratory processed and reported 1,845 out of 1,845 patient samples from June 2025 through November 2025. 5. The TP confirmed on June 11, 2026, at 11:15 a.m.,that the laboratory did not evaluate the accuracy of the Hematology specialty test.
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 Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), hematology proficiency testing (PT) scores (year 2025), laboratory policies and procedures, and interview with the testing personnel (TP) on June 11, 2026, at 11:15 a.m., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with hematology PT requirements. Refer to D5215.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of personnel records and interview with testing personnel (TP) on June 11, 2026, at 8:29 a.m., the laboratory did not document the initial training for one out of one newly hired moderate complexity testing personnel (TP#3) reviewed, before performed patient testing. The findings include: 1. During interview on June 11, 2026, at 8:29 a.m., TP stated that the laboratory hired TP # 3 in Abril 2026. 2. The personnel records for TP#3 did not include documentation of the initial training assessment elements, including: a. Direct observations of routine patient test performance, including patient preparation (if applicable), specimen handling, processing, and testing. b. Monitoring, recording, and reporting test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observation of instrument maintenance and function checks. e. Assessment of test performance through testing of previously analyzed specimens, internal blind samples, or external proficiency testing samples. 3. During interview on June 11, 2026, at 8:45 a.m., TP stated that the laboratory had not performed or documented the initial training for TP#3.