

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0902422	(X3) Date Survey Completed 07/07/2026
Name of Provider or Supplier Laboratorio Clinico Noy & Reference	Street Address, City, State 239 Arterial Hostos, Local 2 Y 1, San Juan, 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 Clinico Noy & Reference on July 7, 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 July 7, 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 supervisor interview on July 7, 2026, at 11:51 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 6,737 patient samples from June 2025 through July 7, 2026. The findings include: 1. The CASPER Report 0155D scores were review on July 7, 2026 at 11:42 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 July 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 July 7, 2026, at 11:51 A.M.; with the laboratory supervisor, the accuracy of the excused hematology

	specialty (Complete Blood Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The laboratory supervisor stated that no procedure for accuracy evaluation was performed. 5. The laboratory supervisor also stated on July 7, 2026, at 11:51 A.M.; that no written procedure was developed by the laboratory to evaluate the accuracy of test not evaluated by the PT provider. 6. From June 2025 through July 7, 2026, the laboratory processed and reported 6,737 patient samples.
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), proficiency laboratory records and interview with the laboratory supervisor on July 7, 2026 at 11:51 AM, the laboratory director failed to verify the accuracy of the hematology proficiency test when the laboratory obtained an artificial score. Refer to D5215.