Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0680512	02/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Camuy Health Services Inc	Calle Munoz Rivera #63, Camuy, 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 Clnico Camuy Health Servives Inc. on February 27, 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 February 27, 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 2024 - 2025), hematology Proficiency Testing (PT) scores (year 2025) and technical supervisor interview on February 27, 2026, at 10:07 a.m., the laboratory failed to evaluate the accuracy of testing in the hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) when the laboratory received an artificially score of 100 percent from the PT provider. The laboratory processed and reported 40,980 patient samples from June 2025 through February 26, 2026. The findings include: 1. PRPTSP were reviewed from February 2024 through December 2025. 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. The results were not evaluated. 3. During interview On February 27, 2025, at 10:10 a.m., with the technical supervisor, the accuracy of the excused hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) was required. The technical supervisor stated that no procedure for accuracy evaluation

	was performed. 4. The technical supervisor on February 27, 2025, at 10:15 a.m, also stated that no written procedure was developed by the laboratory to evaluated the accuracy of test not evaluated by the PT provider. 5. From June 2025 through February 26, 2026, the laboratory processed and reported 40,980 patient samples.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of urinalysis quality control (QC) and maintenance records file (year 2024) and interview with the technical supervisor (TS) on February 27, 2026, at 11:50 a.m., the laboratory failed to verify the performance specifications for the Mission U500 Urine Analyzer prior to performing and reporting patient test results. The laboratory processed and reported 68 out of 68 urinalysis tests results from July 26, 2024, to August 2,2024. The findings include: 1. On February 27, 2026, at 11:50 a.m., the urinalysis QC and maintenance records file showed that on July 26, 2024, the laboratory began to use a loaned Mission U500 Urine Analyzer. 2. The performance specification of the instrument was requested to the TS on February 27, 2026, at 11:55 a.m. The TS stated that no performance specification verification was performed prior to initiate patient testing on July 26, 2024. (February 27, 2026, at 12:08 p.m.) 3. From July 26, 2024, through August 2,2026, the laboratory performed and reported 68 out of 68 patient urinalysis test results.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the lack of performance specification records and interview with the technical supervisor on February 27, 2026, at 1:45 p.m., the laboratory director failed to ensure that the technical supervisor verified the performance specifications for the urinalysis test system prior to performing patient testing and reporting patient test results. Refer to D6115.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

	This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), hematology proficiency testing (PT) scores (year 2025), laboratory policies and procedures, and interview with the technical supervisor on February 27, 2026, at 1:30 p.m., the laboratory director failed to evaluate the accuracy of testing in the hematology specialty (Complete Cell Count - (CBC) and White Blood Cell (WBC) 5 Parameters) and failed to ensure that the laboratory had a written procedure for the evaluation and follow-up of proficiency testing events when the laboratory received an artificially assigned score of 100 percent from the PT provider. Refer to: D5215.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores, urinalysis performance specification records and technical supervisor interview on February 27, 2026, at 1:45 p.m., the technical supervisor failed to fulfill her responsibilities and duties to ensure compliance with the Hematology and Urinalysis requirements. Refer to D5215 and D5421.