Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0680512	02/14/2024
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of general supervisor and clinical consultant records (year 2022-2023) and laboratory general supervisor interview on February 14, 2024 at 9:57 A. M , it was determined that the laboratory failed to follow written policies to assess the clinical consultant and general supervisor competency. The findings include : 1. The laboratory written procedures establishes that the clinical consultant and general supervisor competence evaluation must be performed annually. 2. General supervisor and clinical consultant records were reviewed since January 2022. 3. The laboratory technical supervisor failed to perform the annual competency evaluation to the clinical consultant since May 2021. 4. The laboratory director failed to perform the annual competency evaluation to the general supervisor (technical supervisor) since December 2021.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual, quality assessment records review

	(2022-2023) and laboratory general supervisor interview on February 14, 2024 at 9:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for pre analytic laboratory systems: test request and requisition. The findings include: 1. . Review of the quality assessment procedure manual showed that evaluations to test requisitions must performed each 6 months. 2. Review of the quality assessment records showed that the laboratory did not evaluate the test request and requisitions since April 2023. 3. The laboratory general supervisor confirmed on February 14, 2024 at 9:30 A.M.. that evaluations to test request and requisitions were not performed since April 2023.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A-Based on white blood cells (WBC) differential results comparison records review (year 2022-2023) and laboratory general supervisor interview on February 14, 2024 at 9:40 AM, it was determined that the laboratory failed to evaluate and define each six month the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Sysmex XN 550 hematology system. 2. The laboratory written protocol establishes that the laboratory must be performed the evaluation and define the relationship between test results using different methods each six month. 2. The WBC differential results comparison records showed that the laboratory did not evaluate twice a year the relationship of the WBC differential results between the manual method and the Sysmex XN 550 system since March 2023. 3. The laboratory director confirmed on February 14, 2024 at 9:42 A.M. that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since March 2023. B- Based on laboratory written procedures review, comparison test results records review (year 2022-2023) and interview with the laboratory general supervisor on February 14, 2024 at 9:39 A.M. , it was determined that the laboratory failed to follow the laboratory written procedure to perform and evaluate, each six month , the relationship of the glucose test performed by the Beckman Coulter AU- 480 system and glucometer system since October 2022. The findings include: 1. The laboratory written protocol establishes that the laboratory must be performed the evaluation and define the relationship between test results using different methods (glucose) each six month. 2. The laboratory used the Beckman Coulter AU- 480 system and glucometer to perform glucose test . 3.On February 14, 2024 at 9:39 A..M., review of the laboratory comparison test results showed that the laboratory did not perform the comparison of glucose test since October 2022. 4. On February 14, 2024 at 9:40 A.M., the general supervisor confirmed that the laboratory failed to perform and evaluate twice a year the comparison of glucose test results since October 2022.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment (QA) procedure manual, QA assessment records review (year 2022-2023) and interview with the laboratory general supervisor interview on February 14, 2024 at 9:45 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and the patient's final test reports. The findings include: 1. Review of the quality assessment program showed that evaluations related to the laboratory turn around time and the patient's final test reports. must be evaluated each six month. (review on February 14, 2024 at 9:46 a.m.) 2. Review of the quality assessment record showed that the did not evaluate the turn around time and patient's final test reports since April 2023. (review on February 14, 2024 at 9:46 a.m.) 3. The laboratory genral supervisor confirmed on February 14, 2024 at 9:50 A. M., that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment (QA) records review (year 2022-2023) and laboratory general supervisor interview on February 14, 2024 at 11:45 A.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2022-2023) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. (review on February 14, 2024 at 11:45 a.m.) 2. The laboratory general supervisor confirmed on February 14, 2024 at 11:50 A.M. , that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5209, D5391 , D5391 and D5891.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by:

	Based on personnel records review and laboratory general supervisor interview on February 14, 2024 at 10:07 A.M. , it was determined that the technical supervisor failed to provide annually the competence evaluation to four out of four testing personnel that performed the high and moderate complexity tests since October 2022. The findings include: 1. On February 14, 2024 at 10:10 A.M, review the personnel records showed that the technical supervisor did not evaluate annually the competence of four out four testing personnel; that include at least the following requirements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. The personnel records showed that the competence evaluation were performed on October 2022. 3. On February 14, 2024 at 11:30 A.M, the technical supervisor confirmed that the testing personnel competency were not performed in October 2023.