Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1016052	06/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lab Cl Centro De Certificaciones Medicas Region	Calle Vallejo Esq Garcia Moreno, Rio Piedras, 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) Survey Branch federal surveyors conducted an announced CLIA recertification survey at LAB CL CENTRO DE CERTIFICACIONES MEDICAS REGION on June 12, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the announced routine CLIA recertification survey on June 12, 2024.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the Department of Health (DOH) of Puerto Rico (PR) Public Health Laboratories - Proficiency Testing (PT) Service Program records and interview with the technical consultant (TC), the laboratory failed to have the testing personnel (TP) attest to the examination of the PR PT programs samples for six of six rapid plasma reagin (RPR) testing events from 2022 to 2024. Findings include: 1. On the day of survey, June 12, 2024, review of the PR PT records revealed the following six of six RPR PT attestation documents were only signed by the TP: Events #2 and #3 in 2022. Events #1, #2 and #3 in 2023. Event #1 in 2024. 2. On CMS form 209, the TC is also listed as TP#1. 3. On June 12, 2024, the TC confirmed the findings above and corrected the deficiency onsite at 11:30 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: 42956 Based on observation, a review of temperature records, and an interview with the Laboratory Director (LD), it was determined that the laboratory failed to monitor and document the storage room temperature. Findings: 1. During the survey on June 12, 2024, at approximately 9:30 AM, it was observed that a storage room contained 12 packs of Greiner Bio-One Vacuette Red Tops tubes, which require a storage temperature of 425C (4077F). 2. Review of temperature records indicated that no monitoring or recording of temperatures was conducted for the storage room. 3. In an interview with the LD on June 12, 2024, at 9:45 AM, it was confirmed that the laboratory does not monitor or document the temperature of the storage room.