Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2058420	01/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico La Morenita	Carr 174 Km 10 Hm 2, Bo Guaraguao Abajo, Bayamon, 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 initial CLIA survey at Laboratorio Clinico La Morenita on January 17, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the initial CLIA survey ending on January 17, 2025.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on direct observation, manufacturer's instructions review and laboratory director interview on January 17, 2025 at 11:25 AM, it was determined that the laboratory failed to ensure proper storage for sodium citrate tubes that were not protected from direct light when the laboratory collected 15 patient samples on sodium citrate collection tubes for Prothrombin time (PT) and Partial thromboplastin time (PTT) patient tests for testing referral from October 7, 2024 to January 17, 2025. The findings include: a. On January 17, 2025 at 11:25 AM, the manufacturer's instructions of the BD Vacutainer sodium citrate collection tubes instructed the laboratory to protect from direct light the sodium citrate tubes. b. On January 17, 2025 at 11:25 AM, the laboratory sample collection area was observed. The laboratory uses BD Vacutainer sodium citrate collection tubes. Seven sodium citrate tubes were

	observed stored under direct light. c. From October 7, 2024 to January 17, 2025, the laboratory collected 15 patient samples on sodium citrate collection tubes for referral of PT and PTT samples. d. The laboratory director confirmed on January 17, 2025 at 11:30 AM, that since October 7, 2024 to January 17, 2025, that the laboratory failed to ensure proper storage for sodium citrate tubes that were not protected from direct light.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions review and laboratory director interview on January 17, 2025 at 11:25 AM, it was determined that the laboratory director failed to ensure proper storage for sodium citrate tubes that were not protected from direct light, to provide quality laboratory services for all aspects of the test performance on samples collected in sodium citrate tubes. Refer to D5413.