Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0689290	07/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Munoz Rivera	Esmeralda 51 Munoz Rivera, Guaynabo, 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 Laboratorio Clinico Munoz Rivera on July 10, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on July 10, 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Endocrinology Based on endocrinology instrument Roche Cobas e411 maintenance quality control records, and laboratory supervisor interview on July 10, 2025 at 9:51 AM, it was determined that the laboratory failed to perform the weekly maintenance of the instrument, when 11,116 patient specimens were processed and reported for endocrinology tests from January 1, 2024 to July 10, 2025. The findings include: 1. The laboratory uses the Roche Cobas e411 instrument to perform patient's endocrinology tests. 2. On July 10, 2025 at 9:51 AM, the Roche Cobas e411 instrument maintenance quality control records were reviewed, and showed that the laboratory failed to perform the following weekly maintenance: Clean incubator and aspiration station, and Clean Sipper Probe, when they processed and reported 11,116 patient specimens from January 1, 2024 to July 10, 2025. 3. The laboratory supervisor confirmed on July 10, 2025 at 9:56 AM, that the laboratory did not perform the weekly maintenance of the endocrinology instrument. B. Chemistry Based on chemistry instrument Randox RX daytona maintenance quality control records, and laboratory supervisor interview on July 10, 2025 at 10:24 AM, it was determined that

	the laboratory failed to perform the following instrument maintenance: before starting, daily, weekly, monthly and unscheduled, when 6,600 patient specimens were processed and reported for chemistry tests from January 1, 2024 to July 10, 2025. The findings include: 1. The laboratory uses the Randox RX daytona instrument to perform patient's chemistry tests. 2. On July 10, 2025 at 10:24 AM, the Randox RX daytona instrument maintenance quality control records were reviewed, and showed that the laboratory failed to perform the following instrument maintenance: before starting, daily, weekly, monthly and unscheduled, when they processed and reported 6,600 patient specimens from January 1, 2024 to July 10, 2025. 3. The laboratory supervisor confirmed on July 10, 2025 at 10:29 AM, that the laboratory did not perform the maintenance of the chemistry instrument.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 endocrinology and chemistry instrument maintenance quality control records, and interview with the laboratory supervisor on July 10, 2025 at 10:29 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5411.