Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1043613	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Ginara	1253 Calle Juan Baez Urb San Martin, 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) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Ginara on February 4, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on February 4, 2026, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1212 Condition: Endocrinology 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Human Chorionic Gonadotropin (hCG) quality control records review (years 2024 - 2026) and interview with the laboratory director on February 4, 2026, at 1:25 PM, it was determined that the laboratory failed to meet the quality control requirements for Endocrinology specialty. Refer to D5449.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on the Human Chorionic Gonadotropin (hCG) quality control records review

	(years 2024-2026), and laboratory director interview on February 4, 2026 at 1:25 PM, the laboratory failed to include an external negative and positive control material, each day of patient testing. The laboratory processed and reported 19 hCG patient samples from October 10, 2025 to December 17, 2025. The findings include: 1. The laboratory uses the AimStep Combo Pregnancy kit to perform the hCG tests. 2. Review of the hCG test quality control records (years 2024-2026), on February 4, 2026 at 1:19 PM, showed that the laboratory failed to include an external negative and positive control material, each day of patient testing, when the laboratory processed and reported 19 patient samples from October 10, 2025 to December 17, 2025. 3. The laboratory director confirmed on February 4, 2026 at 1:25 PM, that the laboratory failed to perform the external negative and positive control material each day of patient testing. The laboratory processed and reported 19 patient samples from October 10, 2025 to December 17, 2025.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on urinalysis quality control records review (years 2024-2026) and laboratory director interview on February 4, 2026 at 12:43 PM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials (normal and abnormal controls), when the laboratory processed and reported 487 patient urinalysis samples from January 1, 2025 to February 4, 2026. The findings include: 1. The laboratory performs urinalysis tests with the Mission U500 Urine Analyzer instrument and uses UA liquid Controls Germaine control material. 2. The urinalysis quality control records reviewed (years 2024-2026) on February 4, 2026 at 12:37 PM, from January 1, 2025 to February 4, 2026, showed that there was no evaluation of the manufacturer's stated values for the normal and abnormal kit control material lot number 50941 prior to placing them in routine use on January 1, 2025. 3. The laboratory director stated on February 4, 2026 at 12:43 PM, that no evaluations of the stated lot of control materials were performed prior to placing them in routine use. 4. The laboratory director confirmed on February 4, 2026 at 12:43 PM, that the laboratory failed to evaluate the stated value of the new lot of control materials for urinalysis tests performed by the Mission U500 Urine Analyzer instrument, when they processed and reported 487 patient samples from January 1, 2025 to February 4, 2026.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on Human Chorionic Gonadotropin (hCG) and urinalysis quality control records review (years 2024-2026), and laboratory director interview on February 4, 2026 at 1:25 PM, it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the quality control requirements. Refer to D6007.
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 Human Chorionic Gonadotropin (hCG) and urinalysis quality control records review (years 2024-2026), and laboratory director interview on February 4, 2026 at 1:25 PM, it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the hCG and urinalysis quality control requirements. Refer to D5449 and D5469.