Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658309	07/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico El Paraiso	1648 Parana El Cerezal, San Juan, 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 El Paraiso, on July 18, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on July 18, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1210 Routine Chemitry 42 CFR 493.1212 Endocrinology 42 CFR 493.1441 Moderate Complexity Laboratory Director
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on routine chemistry quality control records review (years 2024-2025) and interview with the laboratory director on July 18, 2025, at 10:30 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry test. Refer to D5447 (A).
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 endocrinology quality control records review (years 2024 - 2025) and interview with the laboratory director on July 18, 2025, at 10:30 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for Endocrinology test. Refer to D5447 (B) .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: A. Based on Prostatic specific antigen (PSA) quality control and patient's test worksheets records review (years 2024-2025), Federal Drug Administration access data base review and laboratory director interview on July 18, 2025, at 9:30 AM, it was determined that the laboratory failed to include two control materials of different concentrations each day of PSA patient's test, when processed and reported 239 out of 315 PSA patient's test from June 1, 2024, to July 17, 2025. The findings include: 1. The laboratory uses NanoEn Tek FREND System to perform PSA patient's tests. 2. Review of Federal Drug Administration access data base on July 18, 2025, at 9:35 AM, showed that the PSA test was classified as moderate complexity test. 3. On July 18, 2025, at 9:45 AM, the PSA quality control and patient's test worksheets records review, showed that the laboratory included two levels of control material each week, instead of two levels of control material, at least each day of patients testing. 4. The laboratory director confirmed on July 18, 2025, at 10:30 AM, that the laboratory processes two levels of control material weekly for PSA patient's test, nor each day of patient's testing. 5. The laboratory processed and reported 239 out of 315 PSA patient's test from June 1, 2024, to July 17, 2025. B. Based on 25 - hydroxyvitamin D (25-OH-D), Testosterone, Thyroxine, free (FT4) and Thyroid stimulating hormone (TSH) quality control and patient's test worksheets records review (years 2024-2025), Federal Drug Administration access data base review and laboratory director interview on July 18, 2025, at 9:30 AM, it was determined that the laboratory failed to include two control materials of different concentrations each day of 25-OH-D, Testosterone, FT4 and TSH patient's tests, when processed and reported 1085 out of 1776 Testosterone, 25-OH-D, FT4 and TSH patient's test from June 1, 2024, to July 17, 2025. The findings include: 1. The laboratory uses NanoEn Tek FREND System to perform: 25-OH-D, Testosterone, FT4 and TSH patient's tests. 2. Review of Federal Drug Administration access data base on July 18, 2025, at 9:35 AM, showed that the 25-OH-D, Testosterone, FT4 and TSH test were classified as moderate complexity test. 3. On July 18, 2025, at 9:45 AM, the endocrinology quality control and patient's test worksheets records review, showed that the laboratory included two levels of control material each week, instead of two levels of control material, at least each day of patients testing. 4. The laboratory director confirmed on July 18, 2025, at 10:30 AM, that the laboratory processes two levels of control material weekly for 25-OH-D, Testosterone, FT4 and TSH patient's tests, nor each day of patient's testing. 5. The laboratory processed and reported 1085 out of 1776 endocrinology patient's test from June 1, 2024, to July 17, 2025.
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 on routine chemistry and endocrinology quality control records review (years 2024-2025), the patient's test worksheets records, Federal Drug Administration access data base review and laboratory director interview on July 18, 2025, at 10:30 AM, it was determined that the laboratory director (sole person) failed to fulfill him responsibilities and duties to ensure compliance with the analytic system for routine chemistry and endocrinology requirements. Refer to D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 routine chemistry and endocrinology quality control records review (years 2024-2025), the patient's test worksheets records, Federal Drug Administration access data base review and laboratory director interview on July 18, 2025, at 10:30 AM, it was determined that the laboratory director (sole person) failed to include two control materials of different concentrations each day of routine chemistry and endocrinology patient's test. Refer to D5447 (A) and (B).