Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2048019	**(X3) Date Survey Completed** 07/31/2025
Name of Provider or Supplier Cdt Eulalia Kuilan Reveron	**Street Address, City, State** Edificio Dr Job Andujar Carr Pr 5 Km 2, Hm 8, Catano, 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 CDT Eulalia Kuilan on July 31, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on July 31, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1210 Condition: Routine Chemistry 42 CFR 493.1403 Condition: Moderate Complexity Laboratory Director In addition, the laboratory was found out of compliance with the following standard level deficiencies found during the recertification CLIA survey on July 31, 2025.
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 general chemistry quality control records review (years 2024-2025) and interview with the laboratory director on July 31, 2025, at 10:40 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for general chemistry test. Refer to D5411, D5447 and D5469.
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: Based on routine chemistry instrument Medica EasyRA maintenance quality control records review, manufacturer's instructions, and laboratory director interview on July 31, 2025 at 11:22 AM, it was determined that the laboratory failed to perform the following instrument monthly maintenance: bleach diluent bottle, bleach waste bottle, clean wash cup, clean ISE cup, and clean filter, when 304 patient specimens were processed and reported from March 1, 2024 to March 31, 2024 for routine chemistry tests, and 206 patient specimens were processed and reported from October 1, 2024 to October 31, 2024 for routine chemistry tests. The findings include: 1. The laboratory uses the Medica EasyRA instrument to perform patient's routine chemistry tests. 2. On July 31, 2025 at 11:12 AM, the Medica EasyRA instrument manufacturer's instructions were reviewed, and showed that the instrument monthly maintenance includes the following: bleach diluent bottle, bleach waste bottle, clean wash cup, clean ISE cup, and clean filter. 3. On July 31, 2025 at 11:16 AM, the Medica EasyRA instrument maintenance quality control records were reviewed, and showed that the laboratory failed to perform the instrument's monthly maintenance, when they processed and reported 304 patient specimens from March 1, 2024 to March 31, 2024 for routine chemistry tests, and 206 patient specimens were processed and reported from October 1, 2024 to October 31, 2024 for routine chemistry tests. 4. The laboratory director confirmed on July 31, 2025 at 11:22 AM, that the laboratory did not perform the monthly maintenance of the routine chemistry instrument from March 1, 2024 to March 31, 2024 when they processed and reported 304 patient specimens, and from October 1, 2024 to October 31, 2024, when they processed and reported 206 patient specimens.
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: Based on lack of chemistry quality control records review (years 2024-2025) and laboratory director interview on July 31, 2025, at 10:12 AM, it was determined that the laboratory failed to include two control materials of different concentrations each day of patient testing, when processed and reported 636 out of 695 Creatine Kinase-MB (CKMB) patient tests, 754 out of 821 Troponin patient tests, and 520 out of 565 Myoglobin patient tests from January 1, 2024, to July 31, 2025. The findings include: 1. The laboratory uses Quidel Triage MeterPro instrument to perform chemistry CKMB, Troponin, and Myoglobin patient tests. 2. On July 31, 2025, at 10:07 AM, review of the chemistry quality control records for CKMB, Troponin, and Myoglobin tests, showed that the laboratory failed to include two control materials of different concentrations each day of patient testing on 636 out of 695 CKMB patient tests, 754 out of 821 Troponin patient tests, and 520 out of 565 Myoglobin patient tests processed and reported from January 1, 2024, to July 31, 2025. 3. The laboratory director confirmed on July 31, 2025, at 10:12 AM, that the laboratory did not include two control materials of different concentrations of CKMB, Troponin, and Myoglobin tests, each day of patient testing from January 1, 2024, to July 31, 2025, when the laboratory processed and reported 636 out of 695 CKMB patient tests, 754 out of 821 Troponin patient tests, and 520 out of 565 Myoglobin patient tests; however she also

	stated and was confirmed that the QC Device, which evaluates calibration, alignment and laser quality control of the instrument, was performed daily. It was also confirmed that two levels of control materials were processed with every reagent lot change.
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 chemistry quality control records review (years 2024 - 2025) and laboratory director interview on July 31, 2025 at 10:40 AM, it was determined that the laboratory failed to verify the stated value of the new lot of control materials, when the laboratory processed and reported 88 Cardiac Panel patient samples from May 22, 2025 to July 15, 2025. The findings include: 1. The laboratory performs chemistry Cardiac Panel tests, which include CKMB, Troponin and Myoglobin, with the Quidel Triage MeterPro system. 2. On July 31, 2025 at 10:35 AM, the chemistry quality control records review (years 2024 - 2025), showed that there was no evaluation of the manufacturer's stated values for the lot numbers 4087AN (control level 1), and 4088AN (control level 2) prior to placing them in routine use on May 22, 2025. 3. The laboratory director confirmed on July 31, 2025 at 10:40 AM, that the laboratory failed to evaluate the stated value of the new lot of control materials for chemistry Cardiac Panel tests performed by the Quidel Triage MeterPro system, when they processed and reported 88 Cardiac Panel patient samples from May 22, 2025 to July 15, 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 quality control records review, manufacturer's instructions review, and laboratory director interview on July 31, 2025 at 11:22 AM, it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the chemistry quality control 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 quality control records review, manufacturer's instructions review, and laboratory director interview on July 31, 2025 at 11:22 AM, it was determined that the laboratory director failed to fulfill her responsabilities and duties to ensure compliance with the chemistry quality control requirements. Refer to D5411, D5447, and D5469.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on chemistry quality control records review and interview with the laboratory director on July 31, 2025 at 11:22 AM, it was determined that the laboratory technical consultant failed to ensure compliance with the chemistry quality control requirements. Refer to D5411, D5447, and D5469.