Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0711813	03/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Cdt Dr Cesar R Rosa Febles	Carr Pr-2 Km 50, Manati, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on March 14, 2024 at 2:00 PM, it was determined that the laboratory failed to evaluate and monitor the patient confidentiality, specimen identification and integrity, complaint investigation, communication, and personnel competency in the general laboratory system since January 2022. The findings include: 1. On March 14, 2024 at 2:00 PM, the general laboratory system QA 2022-2023 records were requested. The general laboratory system QA was not available for evaluation. 2. The laboratory director confirmed on March 14, 2024 at 2:02 PM, that the QA general laboratory system activities records were not evaluated or monitored since January 2022.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2022-2023) and

	laboratory director interview on March 14, 2024 at 2:03 PM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirements for pre-analytic systems since year 2022. The findings include: 1. On March 14, 2024 at 2:03 PM, the laboratory pre-analytic systems QA records 2022-2023 were requested. The pre-analytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: test request, specimen submission and handling, and specimen referral. 3. The laboratory director confirmed on March 14, 2024 at 2:05 PM, that the laboratory pre-analytic systems QA records 2022-2023 were not evaluated or monitored since January 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration verification records, manufacturer's instructions, and laboratory director interview on March 14, 2024 at 10:00 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's instructions (every six months) for the hematology tests performed by the XN-550 hematology system. The findings include: 1. The laboratory uses a XN-550 hematology system for CBC (Complete blood count) patient's tests. 2. Review of the manufacturer's instructions on March 14, 2024 at 10: 02 AM showed that the laboratory must perform the calibration verification procedures every six months. 3. On March 14, 2024 at 10:00 AM, the calibration verification records of XN-550 hematology system showed that the laboratory did not perform at least every 6 months the calibration verification procedures. The calibration verification procedures were done on April 1 2022, and April 11, 2023. 4. The laboratory processed and reported 12,286 CBC patient samples from October 1, 2022 to March 14, 2024. 5. The laboratory director confirmed on March 14, 2024 at 10:05 AM, that the laboratory did not perform at least every 6 months the calibration verification procedures for the XN-550 hematology system.

D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on March 14, 2024 at 01: 18 PM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of patient testing when processing hCG samples. The findings include: 1. The laboratory performed (hCG) human chorionic gonadotropin by Alere hCG Combo Cassette kit. 2. Review of the manufacturer's instructions on March 14, 2024 at 01:15 PM showed that the laboratory must monitor and document the internal control to ensure the validity of the hCG test performed. 3. The hCG test worksheet records showed on March 14, 2024 at 01:18 PM, that the laboratory did not document the observed results of the internal procedural control with each day of patient testing when processing hCG samples. 4. The laboratory processed and reported 207 hCG patient samples from May 1, 2022 to March 14, 2024. 5. The laboratory director confirmed on March 14, 2024 at 01:23 PM, that the laboratory did not monitor and document the internal control with each day of patient testing when processing hCG samples.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on March 14, 2024 at 2:06 PM, it was determined that the laboratory failed to evaluate Quality Assessment Program and monitor the requirements for analytic systems since year 2022. The findings include: 1. On March 14, 2024 at 2:06 PM, the laboratory analytic systems QA records 2022-2023 were requested. The analytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: test procedures, accurate and reliable test system, equipment instruments, reagents, materials, specimen and reagent storage conditions, system naintenance and fucntion checks, verification of method performance specifications, calibration, control procedures, test records, corrective actions, and comparison of test results. 3. The laboratory director confirmed on March 14, 2024 at 2:08 PM, that the laboratory analytic systems QA evaluation records 2022-2023 were not evaluated or monitored since January 2022.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) activities records (years 2022-2023) and laboratory director interview on March 14, 2024 at 2:09 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for postanalytic systems since year 2022. The findings include: 1. On March 14, 2024 at 2:09 PM, the laboratory postanalytic systems QA records 2022-2023 were requested. The postanalytic system QA since year 2022 was not available for evaluation at the time of inspection. 2. Since January 2022 the laboratory did not evaluate practices related to: turn around time and the patient's final test reports. 3. The laboratory director confirmed on March 14, 2024 at 2:11 PM, that the laboratory postanalytic systems QA evaluation records 2022-2023 were not evaluated or monitored since January 2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 hematology and endocrinology quality control records review, it was determined that the laboratory director did not ensure that quality control procedures related to hematology calibration verification and hCG quality control procedures were performed as established by the manufacturer's instructions. Refer to D5439 and D5479.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 lack of the Quality Assessment (QA) records review (year 2022-2023) and laboratory director interview on March 14, 2024 at 2:11 PM, it was determined that laboratory director failed to ensure compliance with QA requirements. Refer to D5291 , D5391, D5791 and D5891.