Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0669530	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Los Robles	#308 Americo Miranda Ave, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review and laboratory director interview on December 12, 2023 at 12:50 PM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results for hemoglobin and hematocrit analytes in the second event of year 2022. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2022 to November 2023. 2. Review of Proficiency Testing records on December 12, 2023 at 12:50 PM, showed that the laboratory obtained an unsatisfactory testing result in the second proficiency testing event of year 2022 of 60% in hemoglobin analyte, and 40% in hematocrit analyte. No remedial actions were taken nor documented for both analytes. 3. The laboratory processed and reported 51 CBC (Complete Blood Count) patient samples from June 1, 2022 to June 30, 2022, that was the proficiency testing period of the second event of hematology of year 2022. 4. The laboratory director confirmed on December 12, 2023 at 12:55 PM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the hemoglobin and hematocrit analytes.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the urinalysis quality control records and laboratory director interview on December 12, 2023 at 9:45 AM, it was determined that the laboratory did not include or document a negative microscopic control material for manual microscopic urinalysis examinations, when 1,080 patients were processed and reported from January 1, 2022 to December 12, 2023. The findings include: 1. The urinalysis quality control records were reviewed on December 12, 2023 at 9:45 AM. 2. The laboratory did not include or document a negative control material for urinalysis microscopy test. 3. The laboratory director confirmed on December 12, 2023 at 9:50 AM, that no negative microscopy control was implemented from January 1, 2022 to December 12, 2023, when 1,080 patients were processed and reported.
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 December 12, 2023 at 11:45 AM, 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. The manufacturer's instructions stated 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 December 12, 2023 at 11:45 AM, that the laboratory did not document the observed results of the internal procedural control each day of patient testing when processing hCG samples. 4. The laboratory processed and reported 8 hCG patient samples from January 1, 2022 to December 12, 2023. 5. The laboratory director confirmed on December 12, 2023 at 11:50 AM, that the laboratory failed to monitor and document the internal control each day of patient testing when processing hCG samples.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing records review and laboratory director interview on December 12, 2023 at 12:50 PM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory proficiency results in the hematology specialty. Refer to D2128.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on urinalysis and hCG worksheet records review from January 1, 2022 to December 12, 2023, and interview with the laboratory director on December 12, 2023 at 11:50 AM, it was determined that the laboratory director (sole personnel) did not ensure that quality control procedures for the urinalysis, nor hCG tests were being followed. Refer to D5445. Refer to D5479.