Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1090756	05/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Avanzado Emmanuel Inc	Carr Pr-149 Km 3 Hm 0 Centro Comercial Monaco, 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
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 reviewed (year 2017-2019) and laboratory director interview on May 17, 2019 at 9:30 A.M., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2017 to April 2019. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 0 percent in PTT (Partial Thromboplastin time) and 20 percent in PT (Prothrombin time) test in November 2018. No remedial actions were taken. 3. The laboratory director confirmed on May 17, 2019 at 9:30 A.M. , that the laboratory failed to take remedial actions when obtained unsatisfactory results of 0 percent in PTT and 20 percent in PT tests in November 2018.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--

	Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of routine chemistry and endocrinology quality control records review (years 2018 to 2019) and interview with the laboratory supervisor and laboratory director on May 17, 2019 at 10:30 AM, it was determined that the laboratory did not verify the acceptability and control range criteria of the control material use for routine chemistry and endocrinology tests. The findings include: a. The laboratory processed routine chemistry and endocrinology tests by the Dimension system. b. From January 4, 2019 to March 4, 2019 the laboratory had in use the following lot numbers: CHA20021A and CHA20023A for routine chemistry and 01M20101A and 01M20103A for endocrinology. c. The laboratory supervisor was interviewed about the laboratory procedure to establish the acceptability and control range of the control material. d. The laboratory supervisor stated on May 17, 2019 at 10:30 A.M.that the laboratory used the data obtained by LIS system to establish their control range. e. From January 4, 2019 to March 4, 2019 the laboratory used the following ranges: low level PSA (prostatic specific antigen) 2.0-4.0 IU/L laboratory range (LR) 0.8-1.2 IU/L manufacturer's range (MR) TSH (thyroid stimulating hormone) 0.15-.53 IU/L (LR) .16-0.24 IU/L (MR) albumin -2.89-14.11 g/dl (LR) 3.5-5.26 g/dl (MR) total bilirubin -2.19-3.81 mg/dl (LR) .78-1.16 mg/dl (MR) calcium 0.36-12.36 mg/dl (LR) 5.0-7.38 mg/dl (MR) glucose 9.58-109.5 mg/dl (LR) 51.2-76.8 mg/dl (MR) potassium 1.2-3.96 mmol/l (LR) 2.15-3.23 mmol/l (MR) f. The laboratory established control ranges were out of the establishes manufacturer's ranges. g. The laboratory director confirmed on May 17, 2019 at 11:00 A.M, that the laboratory failed to verify the control range use for these tests.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: 1. Based on endocrinology quality control records review (year 2018-2019) laboratory general supervisor and laboratory director interview on May 17, 2019 at 11: 45 A.M., it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. The

	findings include: 1. The laboratory performed routine chemistry patient samples by Dimension system. 2. Quality control records were reviewed from January 2018 to April 2019. 3. Review of quality control showed that the laboratory failed to take corrective actions when the control material exceeded the laboratory acceptable limits for the the following test: a. T4 free test (level 2) exceeded the laboratory acceptable limits (below 3 sd) on February 8, 2019. The laboratory processed and reported 2 patient samples this day. 2. Based on routine chemistry quality control records review (year 2018-2019) laboratory general supervisor and laboratory director interview on May 17, 2019 at 11:45 A.M., it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. The findings include: 1. The laboratory performed routine chemistry patient samples by Dimension system. 2. Quality control records were reviewed from January 2018 to April 2019. 3. 25- hidroxy Vitamin D test (level 1, 2) exceeded the laboratory acceptable limits (below 3 sd) from January 4, 2019 to march 4, 2019. four hundred ninety (490) patient samples were processed and reported. laboratory control range level 1 - 19.1-27.1 ng/ml level 2- 43.3-51.2 ng/ml manufacturer range level 1 - 27.7-46.9 ng/ml level 2- 83.1-125 ng/ml 4. The laboratory director confirmed on May 17, 2019 at 11:45 A.M. that no corrective actions were taken and stated that the manufacturer's was doing research in this problem.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2017-2019) and laboratory interview on May 17, 2019 at 11:45 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2128.
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 routine chemistry and endocrinology quality control records review and laboratory director interview on May 17, 2019 at 11:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not verify the acceptability and control range criteria of the control material use for routine chemistry and endocrinology tests. Refer to D5469. 2. The laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. Refer to D5783.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463

	The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on routine chemistry and endocrinology quality control records review and laboratory director interview on May 17, 2019 at 11:30 AM, it was determined that laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not verify the acceptability and control range criteria of the control material use for routine chemistry and endocrinology tests. Refer to D5469. 2. The laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. Refer to D5783.