Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2000974	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Figueroa	Carr Pr-155 Km 58 Hm 5 Barrio Pugnado Adentro, Vega Baja, 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 and laboratory general supervisor interview on February 27, 2018 at 11:00 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 2016 to July 2017. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in PT (Prothombin time) test in March 2017. No remedial actions were taken. 3. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Hematology Cell Identification in March 2017. No remedial actions were taken. 4. The laboratory general supervisor confirmed on February 27, 2018 , that the laboratory failed to take remedial actions when obtained unsatisfactory results in March 2017.
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, calibration verification records and interview with the laboratory general supervisor on February 27, 2018 at 11: 00 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry . Refer to D5405, D5439 and D5791.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on manufacturer's instruction , routine chemistry quality control record review and laboratory general supervisor interview on February 27, 2018 at 11:30 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for routine chemistry test by Dimension EXL-200 system. The findings include: 1. The manufacturer's instruction establishes that two levels of control materials must be included each day of testing (normal and high). 2. The routine chemistry quality control record showed that the laboratory did not include two levels (normal and high) of control materials the following days in April 2017: April 7,14 15 9 (did not include control normal) April 1,5,6,12,13,19,20,23,24,25,26,27 (did not include control high) The laboratory processed and reported 147 Comprehensive metabolic panel on patient samples those days. 3. The routine chemistry quality control record showed that the laboratory did not include the normal level of control materials the following days in July 2017: 1,9,21. The laboratory processed and reported 10 Comprehensive metabolic panel on patient samples those days. 4. On October 2017 , routine chemistry quality control records were reviewed and showed that 4 of 13 days the laboratory did not include the normal level of control. The laboratory processed and reported 94 Comprehensive metabolic panel on patient samples. 5. On November 2017 , routine chemistry quality control records were reviewed and showed that 6 of 20 days the laboratory did not include the normal level of control. The laboratory processed and reported 200 Comprehensive metabolic panel on patient samples.
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 lack of routine chemistry calibration verification records (year 2016 to 2017) and interview with the laboratory supervisor on February 27, 2018 at 11:15 AM, it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests (electrolytes) processed by the Dimension EXL-200 system. The findings include: 1. The laboratory begin to use the Dimension EXL-200 system in November 2015 to perform routine chemistry tests. 2. Review of the calibration verification records showed that the laboratory did not perform the calibration verification for the electrolytes tests (sodium, potassium and chloride) since November 2015. 3. The laboratory supervisor confirmed on February 27, 2018 at 11:15 A.M. that the laboratory did not perform the calibration verification for the electrolytes tests (sodium, potassium and chloride). 4. The laboratory processed and reported 6,961 patient's samples (comprehensive metabolic panel) from January 2016 to January 2018.
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: Based on routine chemistry quality control records review and laboratory general supervisor interview on February 27, 2018 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 EXL-200 system. 2. Quality control records were reviewed from January 2017 to January 2018. 3. Review of quality control showed that the laboratory failed to take corrective actions when the control material exceeded the laboratory acceptable limits the following days: a. On July 6 and July 7, 2018 albumin and blood urea nitrogen (Bun) exceeded the laboratory acceptable limits (below 3 sd) . The laboratory processed and reported 10 patient samples (comprehensive metabolic panel) those days. 4. The laboratory

	general supervisor confirmed on February 27 , 2018 that no corrective actions were taken.
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 quality assessment (QA) records review in 2017-2018 and laboratory general supervisor interview on February 27, 2018 at 11:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for routine chemistry test by Dimension EXL-200 system. Refer to D5405. 2. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests (electrolytes) processed by the Dimension EXL-200 system. Refer to D5439. 3. The laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. Refer to D5783.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on routine chemistry quality control records review and general supervisor interview on February 27, 2018 at 11:45 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system , quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D 6093 and D 6094.
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 proficiency testing records review and laboratory general supervisor interview on February 27, 2018 at 10:00 A.M, 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 quality control, calibration verification records review and interview with the laboratory general supervisor on February 27, 2018 at 11:30 A.M. , it was found that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient specimen were tested for routine chemistry test by Dimension EXL-200 system. Refer to D5405. 2. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests (electrolytes) processed by the Dimension EXL-200 system. Refer to D5439. 3. The laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. Refer to D5783.
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 Quality Assessment (QA) records review and laboratory general supervisor interview at 11:30 a.m. on February 27, 2018 , it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.
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 quality control records review and laboratory general supervisor interview on February 27, 2018 at 11:50 AM, it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 1. The laboratory general supervisor did not evaluate aspects regarding: quality control, calibration verification procedures and correctives actions. Refer to D5405, D5439 and D5783.