Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0658306	**(X3) Date Survey Completed** 01/14/2020
Name of Provider or Supplier Laboratorio Clinico Flores	**Street Address, City, State** Calle Marginal 12 Ave 65 Infanteria, San Juan, 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**
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of calibration verification records (years 2018 and 2019) for the routine chemistry test and laboratory director interview at 9:50 a.m. on January 14, 2020, it was determined that the laboratory failed to retain records that documenting all the calibration verification procedures of the routine chemistry tests from January 2018 to December 2019. The findings include: 1. The laboratory used the Daytona system to perform the CMP and lipid panel tests. 2. The calibration verification records for the routine chemistry test showed that the laboratory performed the calibration verification procedures for CMP and lipid panel tests on August 20, 2018, April 23, 2019 and November 6, 2019. However, the laboratory did not retained the system print out nor the inserts of the calibrator used for those dates (calibrators name, lots numbers and expiration date). 3. The laboratory director confirmed at 9:50 a.m. on January 14, 2020, that the laboratory did not have those records available. 4. The laboratory reported 106,998 out of 106,998 routine chemistry tests from January 2018 to December 2019 by the Daytona system.
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 review of calibration verification records (years 2018 and 2019) for routine chemistry test and laboratory director interview at 9:50 a.m. on January 14, 2020, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry test (comprehensive metabolic panel (CMP) and lipid panel) when the laboratory processed patients specimens and reported 106,998 out of 106,998 routine chemistry tests from January 2018 to December 2019 by the Daytona system. The findings include: 1. The laboratory used the Daytona system to perform the CMP and lipid panel tests. 2. The calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for CMP and lipid panel tests from January 2018 to December 2019 . The records showed that the laboratory performed the calibration verification procedures on August 20, 2018, April 23, 2019 and November 6, 2019. 3. The laboratory director confirmed at 9:50 a.m. on January 14, 2020, the documentation of the calibration verification records. She stated that the laboratory performed a second procedures during the year 2018 but she can not found this documentation. 4. The laboratory reported 106,998 out of 106,998 routine chemistry tests from January 2018 to December 2019 by the Daytona system.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of calibration verification records (years 2018 and 2019) for the

	routine chemistry test and laboratory director interview at 9:50 a.m. on January 14, 2020, it was determined that the laboratory director failed to fulfill her responsibilities and duties to comply with the laboratory retention requirements. Refer to D 3031 (The laboratory failed to retain records that documenting all the calibration verification procedures of the routine chemistry tests from January 2018 to December 2019).
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 review of calibration verification records (years 2018 and 2019) for routine chemistry test and laboratory director interview at 9:50 a.m. on January 14, 2020, it was determined that the laboratory director failed to comply with the analytic requirements for the routine chemistry tests. Refer to D 5439 (The laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry test (comprehensive metabolic panel (CMP) and lipid panel) when the laboratory processed patients specimens and reported 106,998 out of 106,998 routine chemistry tests from January 2018 to December 2019 by the Daytona system).