Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658099	12/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Guaynabo	Herminio Diaz Navarro # 26, Guaynabo, 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
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 routine chemistry calibration verification records review (year 2018 to 2019) and interview with the laboratory supervisor on December 5, 2019 at 11:00 AM, it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (potassium) test processed by the Vitros 250 system. The findings include: a. The laboratory used the Vitros 250 system to process routine chemistry tests. b. Review of the calibration

	verification records showed that the procedures were only performed for potassium test on march and September 2018. c. The laboratory supervisor confirmed on December 5, 2019 that the laboratory failed to perform the calibration verification procedures for potassium test since September 2018. The laboratory processed nad reported 927 patient's electrolytes samples tests since September 2018.
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 calibration verifications records review (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on December 5, 2019, it was determined that the laboratory failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (potassium) test processed by the Vitros 250 system.