Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658051	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier Lab Clinico Loiza Valley Inc	**Street Address, City, State** Z 977 Calle Bauhinia Loiza Valley, Canovanas, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records of the Architect i1000 system for free Thyroxin (T4 free), Vitamin D tests and testing personnel # 4 interview on June 6, 2019 at 10: 55 AM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 713 patients specimens for T4 free and 1,248 patient specimens for Vitamin D from July 1, 2018 to June 5, 2019. The findings include: 1. On June 6, 2019 at 10:55 AM, the Architect i1000 system validation records showed that the laboratory laboratory performed the validation procedures for T4 free and Vitamin D tests in June 2018 and it did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The testing personnel # 4 confirmed on June 6, 2019 at 10:55 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting T4 free and Vitamin D tests patient results. 3. The laboratory processed and reported 713 patients specimens for T4 free and 1,248 patient specimens for Vitamin D from July 1, 2018 to June 5, 2019.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of validation records of the Architect i1000 system for free Thyroxin (T4 free), Vitamin D tests and testing personnel # 4 interview on June 6, 2019 at 10: 55 AM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems for T4 free and Vitamin D tests from July 1, 2018 to June 5, 2019. Refer to D 5421 ((The laboratory did not complete the evaluation of the performance specifications of the new T 4 free and Vitamin D tests performed by the Architect i1000 system, before reporting 713 patients specimens for T4 free and 1,248 patient specimens for Vitamin D from July 1, 2018 to June 5, 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 validation records of the Architect i1000 system for free Thyroxin (T4 free), Vitamin D tests and testing personnel # 4 interview on June 6, 2019 at 10: 55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems for T4 free and Vitamin D tests from July 1, 2018 to June 5, 2019. Refer to D 5421 ((The laboratory did not complete the evaluation of the performance specifications of the new T 4 free and Vitamin D tests performed by the Architect i1000 system, before reporting 713 patients specimens for T4 free and 1,248 patient specimens for Vitamin D from July 1, 2018 to June 5, 2019)