Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1024025	07/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Laurel	Ave Laurel Aq 35 Santa Juanita, Bayamon, 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 and laboratory director interview on July 23, 2021 at 12:05 PM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of following test by the new cobas e 411 analyzer: Thyroxin (T4) free, T4 Total, triiodothyronine (T3) uptake, thyroid stimulating hormone (TSH) , Vitamin-D and prostate specific antigen (PSA) before reporting 4,192 out of 4,192 test results from October 1, 2020 to July 20, 2021. The findings include: 1. The laboratory validated the cobas e 411 analyzer on August 26, 2020 to processed the following tests since October 1, 2020: T4 free, T4 Total, T3 uptake, TSH , Vitamin-D and PSA. 2. On July 23, 2021 at 12:05 PM, the cobas e 411 analyzer validation records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patients tests. 3. The laboratory director confirmed on July 23, 2021 at 12:05 PM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 4. The laboratory processed and reported the following 4,192 patients tests from October 1, 2020 to July 20, 2021: Test Patient's tests reported a. T4 free 347 b. T4 Total 435 c. T3 uptake 337 d. TSH 1910 e. Vitamin-D 796 f. PSA 367

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 validation records review and interview with the laboratory director on on July 23, 2021 at 12:05 PM, it was determined that the laboratory director failed to comply with the requirements of the following tests from October 1, 2020 to July 20, 2021:T4 free, T4 Total, T3 uptake, TSH , Vitamin-D and PSA. Refer to D5421 (The laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting patients tests).