Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658159	07/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Isla Centro - Naranjito	Calle Ignacio Morales Acosta #43, Primer Piso, Naranjito, 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 the Cobas c311 performance verification results and laboratory supervisor interview on July 14, 2023 at 10:35 A.M., it was determined that the laboratory failed to evaluate the instrument's obtained results. The findings include: 1. The laboratory acquired the Cobas c311 chemistry system since November 2021. 2. On July 14, 2023 at 10:35 A.M., the instrument performance verification procedures were reviewed and showed that it was performed on November 11, 2021. The first page of the validation report showed that the laboratory must document the signature, name, title and date of when the obtained results were reviewed and accepted. None of the required information was included. 3. The laboratory supervisor confirmed on July 14, 2023 at 10:40 A.M., that the laboratory director did not evaluate and sign the performance verification of the Cobas c311 chemistry system prior to begin to test patient samples. 4. The laboratory processed and reported 107,250 chemistry tests from November 11, 2021 to July 13, 2023.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on chemistry quality control records review from November 11, 2021 to July 13, 2023, and laboratory supervisor interview on July 14, 2023 at 10:35 A.M., it was determined that the laboratory director failed to fulfill her responsibility to evaluate and sign the performance verification of the new chemistry Cobas c311 system. Refer to D5421.