Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2097128	08/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Plaza Palacios, Inc	Plaza Los Palacios Shopping Ctr, Interseccion Carr, Toa Alta, 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 Immola Rx system for comprehensive metabolic panel (CMP) tests and laboratory director interview on August 7, 2019 at 9:23 AM, it was determined that the laboratory failed to verify that the manufacturer's CMP reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,180 out of 1,180 patient CMP results from April 4, 2019 to August 6, 2019. The findings include: 1. On August 7, 2019 at 9:23 AM, the Immola Rx validation records showed that the laboratory performed the validation procedures on March 29, 2019. However, the laboratory did not verify that the manufacturer's CMP reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The laboratory director confirmed on August 7, 2019 at 9:23 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 CMP patient results since April 4, 2019. 3. The laboratory processed and reported 1,180 out of 1,180 patient CMP results from April 4, 2019 to August 6, 2019.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of validation records of the Immola Rx system for comprehensive metabolic panel (CMP) tests and laboratory director interview on August 7, 2019 at 9: 23 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements of the CMP tests by the Immola Rx system. Refer to D 5421 (The laboratory did not verify that the manufacturer's CMP reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1,180 out of 1,180 patient CMP results from April 4, 2019 to August 6, 2019).