Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1088930	10/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Doctors Village	Carr-102 Km 18 Hm 8 Lighthouse Plaza Hotel, Cabo Rojo, 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
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2017 to 2018) and interview with the laboratory general supervisor on October 31, 2018 at 10:00 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5449 .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on endocrinology quality control records review and interview with the laboratory general on October 31, 2018 at 10:00 AM , it was determined that the

	laboratory failed to include a negative and positive control material when performed hCG test. The findings include : 1. The laboratory performed hCG (human chorionic gonadotropin) by one step method. 2. Endocrinology quality control logs were reviewed from January 2017 to October 2018. 3. The records showed that the laboratory did not include a negative and a positive control material from March 15, 2018 to October 20, 2018. 4. The laboratory performed and reported forty one patient samples during those months. 5. The laboratory general supervisor confirmed on October 31, 2018 at 10:00 A.M, that the laboratory did not include a negative and a positive control material during those months.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2017 to 2018) and interview with the laboratory general supervisor on October 31, 2018 at 10:30 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of Endocrinology for hCG qualitative test. The finding includes: 1. The laboratory director did not comply with the requirements in the subspecialty of Endocrinology for hCG qualitative test. Refer to D 5449.
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 endocrinology quality control records review and laboratory general supervisor interview on October 31, 2018 at 10:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not ensure that a negative and a positive control material were included when performed hCG test. Refer to D5449.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

	This STANDARD is not met as evidenced by: Based on endocrinology quality control records review and laboratory general supervisor interview on October 31, 2018 at 10:30 AM, it was determined that laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory general supervisor did not ensure that a negative and a positive control material were included when performed hCG test. Refer to D5449.