Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658056	07/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Doctor's Center-2, Inc	Calle 11, Bloque 33 Num 17, Ave Roberto Clemente, Villa Carolina, 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
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 director on July 22, 20121 at 11:55 AM, it was determined that the laboratory failed to include each day of testing a negative control and a positive control material when 58 out of 58 patient's specimens were tested for qualitative hCG (Human Chrorionic Gonadotropin) tests from January 23, 2021 to July 9, 2021. The findings include : 1. On July 22, 20121 at 11:55 AM, the testing records showed that the laboratory did not include each day of testing the negative control nor the positive control materials when patients specimens were tested for qualitative hCG. 2. The laboratory run the positive and the negative control procedure for every new hCG Reagent kit lot or shipping kit on January 23, 2021, March 3, 2021 and July 4, 2021. 3. The laboratory director confirmed on July 22, 20121 at 11:55 AM, that the laboratory includes the positive control and the negative control materials every new Reagent kit lot or shipping kit. The laboratory director stated that the internal control were verified and documented for each tests. 4. The laboratory tested and reported 58 out of 58 patient's specimens for qualitative hCG from January 23, 2021 to July 9, 2021.
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 interview with the laboratory director on July 22, 20121 at 11:55 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the hCG tests from January 23, 2021 to July 9, 2021. Refer to D 5449 (The laboratory did not include each day of testing a negative control and a positive control material when 58 out of 58 patient's specimens were tested for qualitative hCG tests from January 23, 2021 to July 9, 2021.