Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0886279	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Hoyamala	Carreter 119 Km 28 7 Bo Hoya Mala, San Sebastian, 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 review of human chorionic gonadotropin (hCG) quality control records (year 2022-2023), patient's test reports, and laboratory supervisor interview on July 13, 2023, at 12:30 PM, it was determined that the laboratory did not include an external negative and positive control material each testing day when performed and reported 10 out of 10 hCG patient's test from April 18, 2023, to June 1, 2023. The findings include: 1. The laboratory performed hCG patient's test by AimStep Combo Pregnancy. (Reviewed on July 13, 2023,2023 at 12:30 PM). 2. The hCG quality control and patient's test reports were reviewed from January 2022 to July 13, 2023. (Reviewed on July 13,2023 at 12:31 PM). 3. The hCG quality control record showed that the laboratory did not include an external negative and positive control material, each testing day, from April 18, 2023, to June 1, 2023. The laboratory only documented the internal procedure control with each patient. (Reviewed on July 13,2023 at 12:40 PM). 4. The laboratory supervisor confirmed that the laboratory did not include an external and positive control material each day of testing. (Reviewed on July 13,2023 at 12:45 PM). 5. The laboratory performed and reported 10 out of 10 patient's specimen were tested for hCG from Abril 18, 2023, to June 1, 2023.
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 review quality control records and interview with the laboratory supervisor on July 13, 2023, at 12:45 PM, it was determined that the laboratory director did not make sure that the technical supervisor maintained the quality control requirements for human chorionic gonadotropin (hCG) patient test. The findings include: 1. The laboratory did not include an external control material for hCG quality control each day of testing. (Refer to D5449)
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on quality control records (year 2022-2023) and the technical supervisor interview on July 13,2023 at 12:45 PM, it was determined that the technical supervisor did not ensure that the testing personnel included an external negative and positive control material each testing day for the hCG patient test. (Refer to D5449)