Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0927289	04/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Marie E	Carr 862 Km 2-7 63b Victoria Heights, Bayamon, 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
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory director interview on April 2, 2024 at 12:35 PM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of patient testing when processing hCG samples. The findings include: 1. The laboratory performed (hCG) human chorionic gonadotropin by OSOM hCG Combo Test kit. 2. Review of the manufacturer's instructions on April 2, 2024 at 12:30 PM showed that the laboratory must monitor and document the internal control to ensure the validity of the hCG test performed. 3. The hCG test worksheet records showed on April 2, 2024 at 12:35 PM, that the laboratory did not document the observed results of the internal procedural control with each day of patient testing when processing hCG samples. 4. The laboratory processed and reported 290 hCG patient samples from January 1, 2023 to April 2, 2024. 5. The laboratory director confirmed on April 2, 2024 at 12:40 PM, that the laboratory did not monitor and document the internal control with each day of patient testing when processing hCG samples.
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 endocrinology quality control records review, it was determined that the laboratory director did not ensure that hCG quality control procedures were performed as established by the manufacturer's instructions. Refer to D5479.