Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2031886	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caribe	Edificio Vale Colon, Carr Pr-111 Km 3, Hm 5, Moca, 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 supervisor interview on March 12, 2024 at 10:58 AM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control observed results of each hCG control level material (two), when the laboratory processed patient samples. The findings include: 1. The laboratory performed (hCG) human chorionic gonadotropin by Aim Step Combo Pregnancy kit. 2. The manufacturer's instructions stated 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 March 12, 2024 at 10:58 AM, that the laboratory did not document the observed results of the internal procedural control of each hcg control material tested when processing patient samples. 4. The laboratory processed and reported 12 hCG control material on the following dates: March 24, 2023, July 5, 2023, October 30, 2023, December 18, 2023, February 21, 2024 and March 11, 2024. A total of six patient samples were tested during the mentioned dates. 5. The laboratory supervisor confirmed on March 12, 2024 at 11:05 AM, that the laboratory failed to monitor and document the internal control of each hCG level control material when processing patient samples.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory supervisor interview on March 12, 2024 at 10:58 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions and laboratory quality control requirements. Refer to D5479.