Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2065872	05/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Vital Care	Centro Comercial Laguna Gardens, Suite 208, 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
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: A. Based on Mycoplasma pneumoniae IgM test manufacturer's instructions, worksheet records review and laboratory supervisor interview on May 8, 2024 at 10: 30 AM, it was determined that the laboratory failed to follow manufacturer's instructions to document the internal control each day of patient testing. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of the manufacturer's instructions on May 8, 2024 at 10:25 AM showed that the laboratory must monitor and document the internal control to ensure the validity of the Mycoplasma pneumoniae IgM test performed. 3. The Mycoplasma pneumoniae IgM test worksheet records showed on May 8, 2024 at 10:30 AM, that the laboratory did not document the observed results of the internal procedural control with each day of patient testing when processing Mycoplasma pneumoniae IgM samples. 4. The laboratory processed and reported 1,133 Mycoplasma pneumoniae IgM patient samples from January 1, 2023 to May 8, 2024. 5. The laboratory supervisor confirmed on May 8, 2024 at 10:35 AM, that the laboratory did not monitor and document the internal control with each day of patient testing when processing Mycoplasma pneumoniae IgM samples. B. Based on Human chorionic gonadotropin (hCG) manufacturer's instructions, worksheet records review and laboratory supervisor interview on May 8, 2024 at 11:20 AM, 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 Aim Step Combo Pregnancy kit. 2. Review of the manufacturer's instructions on May 8, 2024 at 11:15 AM, 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 May 8, 2024 at 11:20 AM, 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 103 hCG patient samples from January 1, 2023 to May 8, 2024. 5. The laboratory supervisor confirmed on May 8, 2024 at 11:25 AM, 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 general immunology and endocrinology quality control records review, it was determined that the laboratory director did not ensure that quality control procedures related to Mycoplasma pneumoniae IgM and hCG quality control procedures were performed as established by the manufacturer's instructions. Refer to D5479.