Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0663834	12/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Centro De Diagnostico Y Tratamiento De	Calle 16 V1 Urb Villa Los Santos, Arecibo, 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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (2020-2021) and interview with the laboratory director on December 2, 2021 at 12:00 P.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material
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 General Immunology (Mycoplasma Pneumoniae test) quality control records review (2020-2021) and interview with the laboratory director on December 2, 2021 at 12:00 PM , it was determined that the laboratory failed to include a

	negative and positive control material when performed Mycoplasma Pneumoniae test by Immuno Card method. The findings include : a. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method. b. Mycoplasma quality control logs were reviewed from 2020 to December 2021. c. The records showed that the laboratory did not include a negative and positive control material from April 20, 2021 to December 2, 2021. The laboratory performed and reported 3,970 mycoplasma patient samples in 2020 and 944 in 2021. d. The laboratory director confirmed on December 2, 2021 at 12:00 P. M., that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma Pneumoniae test by Immuno Card method.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on quality control records review (2020-2021) and laboratory director interview at 12:30 p..m. on December 2, 2021, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093 .
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 Mycoplasma pneumoniae quality control records review (2020-2021) and interview with the laboratory director on December 2, 2021 at 12:30 P.M., it was determined that the laboratory failed to include a negative and positive control material when performed Mycoplasma Pneumoniae test by Immuno Card method. The finding includes: a. The Mycoplasma pneumoniae quality control records showed that no positive neither negative control material were included each day of patient testing. Refer to D5449.