Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0894925	11/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cdt Toa Alta	Calle Barcelo Numero 16, Toa Alta, 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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record random review from Januray 5, 2021 to October 31, 2021 and interview with the laboratory supervisor on Noember 10, 2021 at 10:31 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 26 out of 26 patients specimens were tested and reported for of Mycoplasma pneumoniae from Januray 5 2021; Februrary 17, 2021 and October 16, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. 3. On November 10, 2021 at 10:31 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor or document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from January 5, 2021; February 17, 2021 and October 16, 2021. 4. The laboratory supervisor confirmed on November 10, 2021 at 10:31 AM, that the laboratory did not monitor or document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 26 patient samples for Mycoplasma pneumoniae test from January 5, 2021; February 17, 2021 and October 16, 2021.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and laboratory supervisor interview by phone on November 10, 2021 at 10:31 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the temperature was recorded each day of patient testing from January 5, 2021; February 17, 2021 and October 16, 2021. Refer D5405.