Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2084733	06/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cdt-Centro De Diagnostico Y Tratamiento	Calle Flor Gerena Final, Esq Sergio Pena, Humacao, 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 (year 2021), patient records review and laboratory testing personnel interview on June 16, 2021 at 10:30 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The findings include: 1. The laboratory failed to perform Mycoplasma IgM test as required by manufacturer's instructions by Meridian Immunocard IgM method. Refer to: D5413- The laboratory processed Mycoplasma pneumoniae patient test with below manufacturer's instructions temperature range (22-25). 2. 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review (year 2021) and laboratory testing personnel interview at 10:30 AM on June 16, 2021, it was determined that the laboratory failed to perform Mycoplasma IgM test as required by manufacturer's instructions by Meridian Immunocard IgM method. The findings include: 1. The manufacturers establishes that the Mycoplasma IgM test must be performed at room temperature between 22 C to 25 C. 2. On June 16, 2021 at 10:30 AM, the general immunology records from March 25, 2021 to June 15, 2021 were reviewed. The records showed that the laboratory processed and reported ninety-five (95) Mycoplasma IgM patient's tests samples, with that was performed at temperatures below the established range in the following thirty nine (39) days: Date Temp.C # samples 3/29/21 21.0 2 3/30/21 20.8 8 4/1/21 20.7 1 4/4/21 20.3 3 4/5/21 20.0 3 4/6/21 20.0 1 4/7/21 20.3 1 4/8/21 20.2 2 4/9/21 21.0 2 4/10/21 20.0 3 4/12/21 20.0 1 4/13/21 20.2 4 4/15/21 20.1 2 4/19/21 20.0 3 4/20/21 20.0 1 4/21/21 20.0 3 4/22 /21 20.8 1 4/23/21 20.8 2 4/26/21 20.2 1 4/27/21 21.6 5 4/29/21 20.0 3 4/30/21 20.0 1 5/3/21 20.0 1 5/5/21 20.3 4 5/8/21 20.1 2 5/9/21 21.0 1 5/10/21 20.9 3 5/11/21 20.6 1 5 /12/21 20.0 3 5/13/21 20.0 3 5/14/21 20.0 2 6/7/21 20.0 2 6/8/21 20.9 3 6/9/21 20.0 4 6 /10/21 20.6 1 6/12/21 20.0 2 6/13/21 20.0 2 6/14/21 20.0 6 6/15/21 20.4 2 3. The laboratory testing personnel confirmed on June 16, 2021 that the laboratory performed Mycoplasma IgM tests below the temperature range established by the manufacturer's those days.
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 Mycoplasma pneumoniae IgM quality control results review (year 2021) , patient test results records and the laboratory testing personnel interview on June 16, 2021 at 10:30 AM, it was found that the laboratory did not include a positive and a negative control material each day of patient testing. The findings include: 1. The laboratory began to perform patient's test for Mycoplasma pneumoniae on March 25, 2021. 2. Review of the quality control and patient test results records, on June 16 2021 at 10:30 AM, showed that positive and negative controls were included only when a new reagent box was opened. 3. The quality control and patient test results records showed that from March 25, 2021 to June 15, 2021, the laboratory had a total of 44 days of sample testing. 4. During 40 out of 44 days of testing the laboratory did not include a positive not a negative quality control material. 5. The laboratory testing personnel stated that they included a negative and a positive control material when a new reagent box was opened and documented the procedural control with each patient. 6. The patient test records showed that the laboratory performed a total of ninety-five (95) patient's samples.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, Mycoplasma pneumoniae patient's testing records, general inmunology quality controls review (year 2021) and the laboratory testing personnel interview on June 16, 2021 at 10:30 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of General immunology for Mycoplasma pneumonia IgM tests by Meridian Immunocard method. The finding includes: 1.The laboratory director did not comply with the requirements in the subspecialty of General immunology for Mycoplasma pneumoniae test. Refer to D6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immulogy quality control records review (year 2021) and laboratory testing personnel interview at 10:30AM on June 16, 2021, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not comply with the requirements in the subspecialty of General immunology for Mycoplasma pneumoniae test. Refer to D 5413 and D5449.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review (year 2021) and laboratory testing personnel interview on June 16, 2021 at 10: 30 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5413 and D5449. The finding includes: 1. The laboratory failed to perform Mycoplasma IgM test as required by manufacturer's instructions by Meridian Immunocard IgM method.