Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2159848	**(X3) Date Survey Completed** 12/28/2020
Name of Provider or Supplier Centro De Diagnostico Y Tratamiento Cossma	**Street Address, City, State** Carretera Estatal Pr-9921, Lote 8,, Las Piedras, 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**
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review in 2020 and laboratory director interview at 10:30 AM on December 28, 2020, it was determined that the laboratory failed to perform general immunology test as required by manufacturer's instructions by ImmunoCard Mycoplasma method. The findings include: 1. The manufacturer's establishes that the Mycoplasma IgM test must be performed at room temperature between 22 C to 25 C . 2. Review of general immunology records from April 16, 2020 to December 28, 2020, the records showed that the laboratory processed and reported nine (9) Mycoplasma IgM patient's tests that was performed at temperatures out of range in the following seven (7) days: Date temp.C # samples 7/2/20 21.2 1 7/9/20 20.0 1 7/13/20 21.0 1 7/15/20 21.0 1 8/12/20 20.0 2 8/21/20 20.0 1 8/24/20 21.0 2 3. The laboratory proccessed and reported nine (9) Mycoplasma IgM test patient's samples those days. 4. The laboratory director confirmed that the laboratory performed Mycoplasma IgM test tests below the range established by the manufacturer's those days.
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 in 2020 and laboratory diretor interview at 10:30 AM on December 28, 2020, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The manufacturer's establishes that the Mycoplasma IgM test must be performed at room temperature between 22 C to 25 C . 2. Review of general immunology records from April 16, 2020 to December 28, 2020, the records showed that the laboratory processed and reported nine (9) Mycoplasma IgM patient's tests that was performed at temperatures out of range in the following seven (7) days: Date temp.C # samples 7/2/20 21.2 1 7/9/20 20.0 1 7/13/20 21.0 1 7/15/20 21.0 1 8/12/20 20.0 2 8/21/20 20.0 1 8/24/20 21.0 2 3. The laboratory proccessed and reported nine (9) Mycoplasma IgM test patient's samples those days. 4. The laboratory director confirmed that the laboratory performed Mycoplasma IgM test tests below the range established by the manufacturer's those days. Refer to D5411.
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 manufacturer's instructions, general immunology quality control records review in 2020 and laboratory director interview at 11:30 AM on December 28, 2020, it was found that the laboratory director did not assure that quality control procedures related to perform general immunology test as required by manufacturer's instructions by ImmunoCard Mycoplasma method. The finding includes: 1. The laboratory failed to perform general immunology test as required by manufacturer's instructions by ImmunoCard Mycoplasma method. Refer to 5411.