Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0997753	05/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Best Medical Options	Barrio Mameyal Carr 698, Dorado, 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 manufacturers instructions, general immunology quality control records review (in years 2020-2021) and laboratory general supervisor interview at 10:30 AM on May 27, 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. Review of general immunology records from January 2020 to January 2021, the records showed that the laboratory processed and reported thirty-three (33) Mycoplasma IgM patient's tests that was performed at temperatures below of range in the following twenty- four (24) days: Date temp.C # samples 4/16/20 21.0 1 4/19/20 21.0 2 4/21/20 21.0 1 4/22 /20 21.0 1 4/24/20 21.0 2 4/26/20 21.0 1 5/13/20 21.0 1 5/16/20 21.0 3 5/17/20 21.0 1 5/20/20 21.0 1 5/25/20 21.0 1 5/28/20 21.0 1 6/1/20 21.0 1 6/3/20 21.0 1 6/4/20 21.0 1 6/12/20 21.0 1 6/24/20 21.0 1 7/1/20 21.0 1 7/11/20 21.0 1 7/18/20 21.0 1 7/24/20 21.0 2 7/27/20 21.0 3 8/3/20 21.0 1 8/4/20 21.0 3 3. The laboratory processed and reported thirty-three (33) Mycoplasma IgM patient's samples those days. 4. The laboratory general supervisor confirmed on May 27, 2021 that the laboratory performed Mycoplasma IgM tests below the range established by the manufacturer's those days.
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 manufacturers instructions, general immunology quality control records review (in years 2020-2021) and laboratory general supervisor interview at 10:30 AM on May 27, 2021, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5413. The finding includes: 1. The laboratory failed to perform Mycoplasma IgM test as required by manufacturer's instructions by Meridian Immunocard IgM method.
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 years 2020-2021) and laboratory general supervisor interview at 10:30 AM on May 27, 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. Review of general immunology records from January 2020 to January 2021, the records showed that the laboratory processed and reported thirty-three (33) Mycoplasma IgM patient's tests that was performed at temperatures below of range in twenty-four (24) days.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on manufacturers instructiions, general immunology quality control records review(years 2020-2021) and laboratory general supervisor interview at 10:30 AM on May 27, 2021, it was determined that the general supervisor did not assure that quality control procedures were followed as established by the manufacturers instructions by the testing personnel. Refer to 5413.