Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0968618	01/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Y Bacteriologico Jaimar	Carr 402 Km 2 Bo Marias, Anasco, 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
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 Immuno Card Mycoplasma manufacturer's instructions, general immunology quality control records review (years 2022-2023) and laboratory general supervisor interview on January 20, 2023 at 10:25 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to December 21, 2022. The findings include: 1. The laboratory use Immuno Card Mycoplasma (Meridian to perform Mycoplasma patient's sample test. 2. The manufacturer's instruction establishes that the Mycoplasma test must be at room temperature between 22 to 25 C reviewed at 10:25 AM. 2. On January 20, 2023 at 10: 30 AM, the Mycoplasma testing records showed that the laboratory did not follow the manufacturer's instructions when it processed the following patients specimens: Testing Temperature Date processed #samples 1/3/2022 20.9 C 1 1/7/2022 20.4 C 1 1 /8/2022 20.8 C 1 1/10/2022 20.8 C 3 1/11/2022 21.3 C 4 1/12/2022 20.5 C 3 3/2 /2022 20.8 C 2 3/25/2022 21.6 C 3 3/28/2022 20.8 C 8 3/30/2022 20.8 C 5 3/31 /2022 21.8 C 2 4/4/2022 21.8 C 6 4/5/2022 21.8 C 2 4/8/2022 21.8 C 2 4/9/2022 21.8 C 3 4/20/2022 21.0 C 8 4/21/2022 21.1 C 2 5/11/2022 25.5 C 11 5/16/2022 25.6 C 6 5/17/2022 25.6 C 7 5/18/2022 26.0 C 6 5/19/2022 25.9 C 2 5/25/2022 21.2 C 4 5/26/2022 21.1 C 6 5/27/2022 21.1 C 1 5/28/2022 21.2 C 4 6/4/2022 25.8 C 2 6

	/13/2022 25.3 C 5 6/16/2022 20.9 C 2 6/27/2022 21.8 C 2 8/6/2022 25.1 C 1 8/29 /2022 25.4 C 3 9/21/2022 26.0 C 2 9/30/2022 21.9 C 1 10/3/2022 25.9 C 4 10/8 /2022 21.3 C 1 10/22/2022 21.9 C 1 11/1/2022 25.2 C 6 11/2/2022 25.3 C 15 11/3 /2022 25.9 C 13 11/9/2022 25.0 C 14 11/25/2022 25.5 C 1 11/28/2022 25.1 C 9 12 /21/2022 21.3 C 7 3. The laboratory general supervisor confirmed on January 20, 2023 at 11:50 AM, that the laboratory did not follow the manufacturer's instructions for the temperature of processing. 4. The laboratory processed and reported patient's specimen for mycoplasma test 192 out of the manufacturer's temperature range from January 3, 2022 to December 21, 2022 reviewed at 11:50 AM.
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 (years 2022-2023) and laboratory general supervisor interview on January 20 2023 at 10:25 AM, it was determined that the laboratory failed to include an external positive and negative control material each day when performed Mycoplasma pneumoniae patient testing by Immuno Card Mycoplasma (Meridian). The findings include: 1. The laboratory performed Mycoplasma patient's tests by ImmunoCard Mycoplasma (Meridian). 2. The general immunology quality control records were reviewed from January 1, 2022 to January 19, 2023. Reviewed at 10:25 AM. 3. From January 1, 2022 to January 19, 2023, the records showed that the laboratory did not include a negative and positive control material each day of patient's testing since January 3, 2022. The laboratory include a negative and positive control only one time weekly. Reviewed at 11:30 AM. 4. The laboratory general supervisor confirmed on January 20, 2023 at 11:45 AM, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 5. The laboratory did not include any control material, when 138 out 162 days patient's specimens were processed from January 3, 2022 to September 30, 2022. 6. The laboratory processed and reported four hundred sixty two (462) Mycoplasma patient's samples out of a total one thousand forty eight (1,148) patient's samples 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 Mycoplasma ImmunoCard (Meridian) manufacturer's instructions, general immunology quality control records review (years 2022-2023)and laboratory testing personnel interview on February 14, 2017 at 10:00 AM, it was determined that testing

	personnel failed to follow quality control procedures. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to December 21, 2022. Refer D5413. 2. The laboratory failed to include an external positive and negative control material each day when performed Mycoplasma pneumoniae patient testing by Immuno Card Mycoplasma (Meridian). Refer D5449.
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 ImmunoCard (Meridian) manufacturer's instructions, general immunology quality control records review (years 2022-2023)and laboratorygenral supervisor interview at 10:50 AM on January 0, 2023, it was determined that laboratory director failed to ensure to follow the manufacturer's instruction when patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to December 21, 2022. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to December 21, 2022. Refer D5413. 2. The laboratory failed to include an external positive and negative control material each day when performed Mycoplasma pneumoniae patient testing by Immuno Card Mycoplasma (Meridian). Refer D5449.