Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0927289	04/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Marie E	Carr 862 Km 2-7 63b Victoria Heights, Bayamon, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from March 1, 2021 to April 8, 2022 and laboratory director interview, it was determined that the laboratory failed to follow the manufacturer's instruction when 637 out of 637 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 1, 2021 to April 8, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On April 8, 2022 at 10:34 AM, the Mycoplasma

	testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 1, 2021 to April 8, 2022. 3. The laboratory director confirmed on April 8, 2022 at 11:31 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 637 out of 637 patients specimens for mycoplasma test by Immuno Card Meridian method from March 1, 2021 to April 8, 2022.
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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from March 1, 2021 to April 8, 2022 and laboratory director interview on April 8, 2022 at 11:31 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction for monitor and documented the room temperature when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. The finding includes: 1. The laboratory did not follow the maufacturer's instruction for monitor and documented the room temperature from March 1, 2021 to April 8, 2022 when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5403.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from March 1, 2021 to April 8, 2022 and laboratory director interview on April 8, 2022 at 11:31 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's were tested for Mycoplasma by Immuno Card Meridian Method. The finding includes: 1. The laboratory testing personnel did not follow the manufacturer's instruction for monitor and documented the room temperature from March 1, 2021 to April 8, 2022 when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5403.