Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0710605	09/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caribe	Munoz Rivera 35, Rincon, 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 laboratory room temperature and relative humidity records review (years 2022-2023) and laboratory general supervisor interview at 11:15 AM. on September 26, 2023, it was determined that the laboratory failed to monitor the room temperature and relative humidity as establishes. The findings include: 1. The laboratory room temperature and relative humidity records were reviewed from January 2, 2023 to September 25, 2023. Reviewed at 11:15 AM. 2. The laboratory establishes that the room temperature must be between 23 to 30 C and relative humidity was between 35 to 70 %. Reviewed at 11:20 AM. 3. From January 2, 2022 to September 25, 2023, the records showed that the laboratory documented temperatures below 23 C on 85 out of 205 days;and relative humidity below 35 % on 173 out of 205 days. Reviewed at 11: 35AM. 4. The laboratory general supervisor confirmed on September 26, 2023 at 11: 40 AM that the laboratory failed to monitor the room temperature and relative humidity as established.
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 (Mycoplasma pneumoniae) testing record review from March 2, 2023 to September 25, 2023 and interview with the laboratory general supervisor on September 26, 2023 at 10:10 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 155 out of 155 patients specimens were tested and reported for of Mycoplasma pneumoniae from March 2, 2023 to September 25, 2023. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. (review on September 26, 2023 at 10: 10 A.M.) 3. On September 26, 2023 at 10:30 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from March 2, 2023 to September 2023. 4. The laboratory general supervisor confirmed on September 26, 2023 at 10:40 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 155 out of 155 patient samples for Mycoplasma pneumoniae test from March 2, 2023 to September 26, 2023.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of preventive maintenance of the laboratory equipments (years 2022-2023) and laboratory general supervisor interview on September 26, 2023 at 9: 30 AM, it was determined that the laboratory failed to perform the preventive maintenance of the following equipments: centrifuge, microscope, rotator and mixer annually as established. The findings include: 1. The laboratory stablishes as preventive maintenance of the following equipments centrifuge, microscope, rotator and mixer must be perform annually. Reviewed at 9:30 AM. 2. The laboratory equipment (centrifuge, microscope, rotator and mixer) showed a label that indicates that the last certification was peformed on September 2021. Reviewed at 9:40 AM. 3. The laboratory general supervisor confirmed on September 26, 2023 at 9:450 AM, that these preventive maintenance must be perform annually and that the laboratory failed to ensure that these preventive maintenance were performed as establishes.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review (years 2022-2023) and laboratory general supervisor interview on September 26,2023 at 10:40 AM, it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. The findings include: 1. From January 14, 2022 to September 25, 2023, the records showed that the laboratory did not check nor document the reactivity of Wright's stain reagent, each day of use, since January 2, 2023. 2. The laboratory processed and reported nineteen (19) WBC (white blood cell) differential manual since January 2, 2023. 3. The laboratory general supervisor confirmed on September 26, 2023 at 10:40 AM, that the laboratory failed to check, each day of use, the Wright's stain used in hematology.
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 hematology quality control records review (years 2022-2023), general immunology quality control records review (years 2022-2023), room temperature and relative humidity records review (years 2022-2023), preventive maintenance for equipments records review (2022-2023) and laboratory general supervisor interview at 11:45 AM on September 26, 2023, it was found that the laboratory director did not assure that quality control procedures related to evaluation of Wright stain for WBC (White blood cell) differential manual, laboratory maintenance equipments, follow manufacturer's instruction for Mycoplasma patient's tests and monitor room temperature and relative humidity as established. Refer to D5411, D5413, D5435 and D5473.
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 hematology quality control records review (years 2022-2023), general immunology quality control records review (years 2022-2023), room temperature and

	relative humidity records review (years 2022-2023), preventive maintenance for equipments records review (2022-2023) and laboratory general supervisor interview at 11:45 AM on September 26, 2023, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5411, D5413, D5435 and D5473.