Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1099014	06/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Del Atlantico	Carr Pr-2 Km 78 Hm 02 Ave Miramar 860, Arecibo, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2022-2023) and laboratory general supervisor interview on June 8, 2023 , it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2022 to May 2023. (review on June 8, 2023 at 10:00 a.m.) 2. The review of records showed that the laboratory director and laboratory general supervisor (testing personnel) did not sign the attestation statements of the Proficiency testing records from February 2022 to May 2023. (review on June 8, 2023 at 10:00 a.m.) 3. The laboratory general supervisor confirmed on June 8, 2023 at 10:05 a.m. that the laboratory director and general supervisor (testing personnel) failed to sign the attestation statements in 2022-2023.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

	This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from January 2022 to June 7, 2023 and interview with the laboratory general supervisor on June 8, 2023 at 10:20 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 1551 out of 1551 patients specimens were tested and reported for of Mycoplasma pneumoniae since January 2022. 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 June 8, 2023 at 10:20 A.M.) 3. On June 8, 2023 at 10:25 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 since January 2022. 4. The laboratory general supervisor confirmed on June 8, 2023 at 10:30 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 736 (year 2022) and 815 (year 2023) patient samples for Mycoplasma pneumoniae test.
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 RPR test manufacturer's instructions, syphilis serology work sheets records review (year 2022-2023) and laboratory general supervisor interview on June 8, 2023 at 10:35 AM, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method. The findings include: 1. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 20 C to 30 C . 2. Review of syphilis serology work sheets records from January 2022 to June 8, 2023, showed that the laboratory established in the RPR that the RPR tests must be perform at room temperature between 23 C to 29 C . 3. The laboratory general supervisor confirmed on June 8, 2023 at 10:40 a.m., that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method.
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 pneumonia IgM quality control records , syphilis serology work sheets records review (year 2022-2023) and interview with the laboratory general supervisor on June 8, 2023 at 10:40 AM, it was determined that the laboratory

	director failed to ensure compliance with the requirements for analytic systems. Refer to D5405- the laboratory failed to follow the manufacturer's instruction when 42 out of 42 patients specimens were tested and reported for of Mycoplasma pneumoniae since January 2022. D5411 - the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by ASI RPR method.
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 Mycoplasma pneumonia IgM quality control records , syphilis serology work sheets records review (year 2022-2023) and interview with the laboratory general supervisor on June 8, 2023 at 10:40 AM, it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D5405 and D5411.