Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0682041	09/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Lecord	Ave De La Constitucion 260 Suite 1, San Juan, 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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the Mycoplasma pneumoniae IgM quality control records on September 12, 2023 at 11:20 A.M., and laboratory director interview, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.
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 Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review on September 12, 2023 at 11:20 A.M., and laboratory director interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma

	pneumoniae IgM quality control and patient test worksheet records on September 12, 2023 at 11:20 A.M., showed that the laboratory did not include any control material each day of patient testing from January 1, 2022 to September 12, 2023, when 467 out of 467 patients were processed and reported. 3. The laboratory director confirmed on September 12, 2023 at 11:30 A.M., that the laboratory failed to include a negative and positive control material each day of patient testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae IgM quality control records review, and laboratory director interview on September 12, 2023 at 11:20 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.
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 pneumoniae IgM quality control records and interview with the laboratory director on September 12, 2023 at 11:20 AM, it was determined that the laboratory director did not ensure to include a positive and a negative control material each day of patient testing. Refer to D5449.