Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2252804	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Jaimar Ii	Carr 4416 Km 0 Hm 6 Interior Bo Piedras Blancas, Aguada, 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 Mycoplasma pneumoniae test quality control records and patient records review (year 2022) and interview with the laboratory director on November 17, 2022 at 9:00 A.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of patient testing. 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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2022) 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 patient testing. The findings include: 1. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method. 2. General Immunology (Mycoplasma pneumoniae test) quality control records were review on November 17, 2022 at 9:00 A.M., from September 21, 2022 to November 16, 2022. 3. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since September 21, 2022 . (review on November 17, 2022 at 9:05 a. m.) 4. The laboratory director confirmed on November 17, 2022 at 9:10 A.M, 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 35 out 35 patient specimen were processed and since September 21, 2022 . (review on November 17, 2022 at 9:05 a.m.)
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records review (year 2022) and laboratory director interview on November 17, 2022 at 9:20 A.M, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D 6020.
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 Mycoplasma pneumoniae testing records review (year 2022) and laboratory director interview on November 17, 2022 at 9:20 a.m. , it was determined that the laboratory director failed to ensure that the laboratory follow to ensure compliance with the requirements for analytic systems. Refer to D5449.