Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0717794	02/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Roman	Ave Jose De Diego #208, 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
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 quality control records patient records review and interview with the laboratory general supervisor on February 4, 2021 at 9:30 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material
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 review of Mycoplasma pneumonia IgM quality control results (year 2020-2021) , patient test results records and interview with the laboratory general supervisor on February 4, 2021 at 9:30 AM, it was found that the laboratory did not include a positive and a negative control material each day of patient testing. The

	findings include: 1. The laboratory began to perform patient's test for Mycoplasma pneumonia on April 6, 2020. 2. Review of the quality control and patient test results records on February 4, 2021 at 9:30 AM, showed that positive and negative controls were included when a new reagent box was opened. 3. The patient records showed that the laboratory the laboratory did not include a positive not a negative quality control material each day of testing. 4. The laboratory supervisor stated that they included a negative and a positive control material when a new reagent box was opened and documented the procedural control with each patient. 5. The patient test records showed that the laboratory performed a total of 134 Mycoplasma pneumonia patient's samples since April 6, 2020.
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 quality control records review and laboratory supervisor interview on February 4, 2021 at 9:30 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 pneumonia IgM quality control records and interview with the laboratory general supervisor on February 4, 2021 at 9:300 AM, it was determined that the laboratory director did not make sure to include a positive and a negative control material each day of patient testing for Mycoplasma pneumonia tests. Refer to D5449.
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 (year 2020-2021) and interview with the laboratory general supervisor on February 4, 2021 at 9:30 AM, it was determined that the general supervisor failed to follow quality control procedures. Refer to D5449.