Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1071152	12/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Llanadas	Carr 140 Km 67, Barceloneta, 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
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) testing records review from October 27, 2021 to December 6, 2021 and interview with the laboratory supervisor on December 7, 2021 at 9:59 AM, it was determined that the laboratory did not include an external positive and negative control material when 16 out of 16 patients specimens were tested and reported for Mycoplasma pneumoniae from October 27, 2021 to December 6, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. On December 7, 2021 at 9:59 AM, Mycoplasma pneumoniae testing record review showed that the laboratory performs and report patient sample from October 27, 2021 to December 6, 2021. The laboratory did not include a external positive and negative control each day of patient testing. 3. The laboratory supervisor confirmed on December 7, 2021 at 9:59 AM, that the laboratory failed to include each day of patient testing an external negative and positive control material . She stated that the laboratory run the external controls when it received a new reagent kit. 4. The laboratory processed and reported 16 patients specimens for Mycoplasma pneumoniae from October 27, 2021 to December 6, 2021.
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 rapid test quality control records and interview with the laboratory supervisor on December 7, 2021 at 9:59 AM, it was determined that the laboratory director did not assure that external control was run each day of patient testing. Refer to D5449.