Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2054127	01/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico La Monserrate	Edificio Comercial Belmonte Centro, Mayaguez, 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
D0000	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clnico La Monserrate on January 14, 2025 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey on Janury 14, 2025.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on the Mycoplasma pneumoniae Individual Quality Control Plan (IQCP) reviewed and laboratory director interview on January 14, 2025 at 10:45 A.M., it was determined that the laboratory did not include specific information of the in house data used to perform the risk assesment evaluation (RA). The findings include: 1. The laboratory director stated on January 14, 2025 that,since November 2024, the laboratory implemented a reduced quality control frequency for Mycoplasma pneumoniae test. 2. Review of the approved IQCP documents showed that the laboratory did not include the in house data to evaluate the RA,QC (quality control) and QA (quality assesment) plan. 3. Review of the Mycoplasma pneumoniae quality control records showed that the laboratory performed quality control procedures with

	each new lot or box instead of each day of testing. 4. The laboratory processed and reported 34 mycoplasma patients samples since November 2024.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 IQCP plan reviewed and laboratory director interview on January 14, 2025 at 11:15 A.M. it was determined that the laboratory director did not assure that the in house data were included for the evaluation of the Mycoplasma pneumoniae IQCP plan. Refer to D5445.