

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658242	(X3) Date Survey Completed 01/22/2025
Name of Provider or Supplier Laboratorio Clinico Doctor Center Miramar	Street Address, City, State Ave Ponce De Leon 670, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Doctor Center Miramar on January 22, 2025. 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 ending on January 22, 2025.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(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:</p> <p>This STANDARD is not met as evidenced by: A. Based on the Mycoplasma pneumoniae Individualized Quality Control Plan (IQCP), quality control records reviewed and laboratory director interview on January 22, 2025 at 11:10 A.M., it was determined that the laboratory did not perform the risk assessment (RA) evaluation. The laboratory processed and reported 119 patients sample since from April 29, 2024 to December 31, 2024. The findings include: 1. Review of the Mycoplasma pneumoniae quality control records on January 22, 2025 at 11:00 A.M., showed that the laboratory performed the quality control procedures with each new lot or new open box instead of each day of patient testing. 2. The laboratory director stated on January 22, 2025 at 11:10 A.M., that the IQCP was implemented on April 29, 2024 to reduced the quality control frequency for</p>

Mycoplasma pneumoniae test. 3. Review of the approved IQCP documents showed that the laboratory did not performed the risk assessment evaluation. 4. The laboratory director confirmed on January 22, 2025 at 11:10 A.M., that the risk assessment of the Mycoplasma pneumoniae IQCP was not performed. The laboratory processed and reported 119 patients sample since from April 29, 2024 to December 31, 2024. B. Based on the Human Chorionic Gonadotropin (hCG) Individualized Quality Control Plan (IQCP) , quality control records reviewed and laboratory director interview on January 22, 2025 at 10:52 A.M., it was determined that the laboratory did not perform the risk assessment (RA) evaluation. The laboratory processed and reported 27 patients sample from May 1, 2024 to December 18, 2024. The findings include: 1. Review of the hCG quality control records on January 22, 2025 at 10:45 A.M., showed that the laboratory performed the quality control procedures with each new lot or new open box instead of each day of patient testing. 2. The laboratory director stated on January 22, 2025 at 10:49 A.M., that the IQCP was implemented on April 29, 2024 to reduced the quality control frequency for hCG test. 3. Review of the approved IQCP documents showed that the laboratory did not performed the risk assessment evaluation. 4. The laboratory director confirmed on January 22, 2025 at 10:52 A.M., that the risk assessment of the hCG IQCP was not performed. The laboratory processed and reported 27 patients sample from May 1, 2024 to December 18, 2024.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(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 and Human chorionic Gonadotropin IQCP plan reviewed, quality control records and laboratory director interview on January 22, 2025 at 11:15 A.M. it was determined that the laboratory director did not assure that the risk assessment evaluation for the IQCP plan were performed for Human chorionic Gonadotropin and Mycoplasma pneumoniae. Refer to D5445.