

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0692386	(X3) Date Survey Completed 10/08/2024
Name of Provider or Supplier Laboratorio Clinico Rios Lisojo	Street Address, City, State #4 Calle Palmer, Las Marias, 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 CLINICO RIOS LISOJO on October 8, 2024. 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 October 8, 2024.
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2023-2024) and laboratory general supervisor interview on October 8, 2024 at 10:00 AM, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2023-2024) and laboratory general supervisor interview on October 8, 2024 at 10:00 AM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient's sample testing by Inmunocard IgM -Meridian. The findings include: 1. The laboratory uses Inmunocard IgM- Meridian to perform Mycoplasma pneumoniae patient's samples tests. 2. The General Immunology (Mycoplasma pneumoniae test) quality control records were review since January 2023 to October 7, 2024 3. Review of Mycoplasma pneumoniae quality control and patient results record since January 2, 2024 to October 7, 2024, showed that the laboratory did not include any control material each day of patient testing in 148 out of 161 days. Review October 8, 2024 at 10:10 AM. 4. The laboratory general supervisor confirmed on October 8, 2024 at 10:25 AM, 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 384 out of 384 patient's specimen were processed and reported since January 2, 2024.

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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2023-2024) and laboratory general supervisor interview on October 8, 2024 at 10:00 AM it was determined that the laboratory director failed to ensure that quality procedures were maintained by the testing personnel in charge of M. pneumoniae 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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2023-2024) and laboratory general supervisor interview on October 8, 2024 at 10:00 AM. it was determined that the laboratory general supervisor did not oversight the laboratory procedures related to the quality control procedures for M. pneumoniae test performed by the testing personnel. Refer to D5449.