

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658115	(X3) Date Survey Completed 09/24/2021
Name of Provider or Supplier Cardona Lamela Clinical Lab	Street Address, City, State Calle San Antonio 94a, Isabela, 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	<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 Mycoplasma pneumoniae quality control records patient records review and interview with the laboratory supervisor on September 24, 2021 at 11:04 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: D 5449</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: Based on General Immunology (Mycoplasma pneumoniae test) quality control records review from January 15, 2021 to May 12, 2021 and interview the laboratory supervisor on September 24, 2021 at 11:04 AM, it was determined that the laboratory did not include an external positive and negative control material each day of</p>

	<p>Mycoplasma pneumoniae patient testing. The findings include: 1. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method 2. Review of Mycoplasma pneumoniae quality control at patient results record showed that the laboratory performs patient testing from January 15, 2021 to May 12, 2021 the laboratory did not include any control material each day of patient testing. 3. From January 15, 2021 to May 12, 2021 the laboratory processed and reported a total of 54 patient samples. 4. The laboratory supervisor confirmed on September 24, 2021 at 11:04 AM, that the laboratory failed to include a negative and positive control material in these days of testing when performed Mycoplasma pneumonia test.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on General Immunology quality control records review and laboratory supervisor interview on September 24, 2021 11:04 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory general immunology quality control requirements. Refer to D 6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on general immunology quality control records review and interview with the laboratory supervisor on September 24, 2021, it was determined that the laboratory director, did not assure that a quality control program was implemented for Mycoplasma pneumoniae test. Refer to D 5449 (The laboratory did not include any control material when patient test were tested for Mycoplasma pneumoniae)</p>