

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0668343	<b>(X3) Date Survey Completed</b> 02/17/2022
<b>Name of Provider or Supplier</b> Cdt-Centro De Salud Mariano Rivera Ramos	<b>Street Address, City, State</b> 174 Luis Barreras St, Cayey, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> 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) testing records review ( years 2021 to 2022) and interview with the laboratory director, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 55 out of 55 patients specimens were tested and reported for of Mycoplasma pneumoniae from February 2, 2021 to September 24, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. On February 17, 2022 at 11:03 AM, review of Mycoplasma pneumoniae testing record showed that the laboratory performed patient testing from February 2, 2021 to September 24, 2021. The laboratory did not include each day of testing the externals (positive nor the negative) control materials. 3. The laboratory director confirmed on February 17, 2022 at 11:10 AM, that the laboratory failed to include each day of testing the 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 55 patients specimens for Mycoplasma pneumoniae from February 2, 2021 to September 24, 2021.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on General Immunology (*Mycoplasma pneumoniae* test) testing records review ( years 2021 to 2022) and interview with the laboratory director , it was determined that the laboratory director to failed to ensure compliance with the analytic system requirements of General Immunology specialty from February 2, 2021 to September 24, 2021. Refer to D 5449 (The laboratory did not include each day of testing an external positive and negative control material when 55 out of 55 patients specimens were tested and reported for of *Mycoplasma pneumoniae* from February 2, 2021 to September 24, 2021).