

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0699932	<b>(X3) Date Survey Completed</b>  10/11/2023
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Country Club	<b>Street Address, City, State</b>  Ave Campo Rico 758 C Club, San Juan, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on ImmunoCard Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records, and laboratory director interview on October 11, 2023, at 12:20 PM; it was determined that the laboratory failed to follow manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test. The findings include: 1. The manufacturer's instructions establish to perform the test procedures between 22 to 25C. 2. On October 11,2023 at 12:20PM, the Mycoplasma pneumoniae testing records showed that from January 9, 2023 to October 6, 2023, the laboratory processed and reported 57 out of 107 patient's specimens with a temperature range within 19 to 21C. 3. The laboratory director confirmed during interview on October 11,2023 at 12:37 PM, that the laboratory processed patient's samples outside the established temperature range.</p>
<b>D6068</b>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425</p> <p>The testing personnel are responsible for specimen processing, test performance, and for reporting test results.</p>

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and laboratory director interview on October 11,2023, at 1:00 PM it was determined that the testing personnel did not follow the written instructions, when she processed 57 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.