

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0671732	(X3) Date Survey Completed 11/03/2023
Name of Provider or Supplier Laboratorio Clinico Levittown	Street Address, City, State Lealtad S 15 Levittown Station, Toa Baja, 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
D5413	<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 interview with the laboratory general supervisor on November 3, 2023, at 1:15 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. (Reviewed on November 3,2023 at 1:15 P.M.) 2. On November 3,2023 at 1:20PM, the Mycoplasma pneumoniae testing records showed that from December 26, 2022 to November 2, 2023, the laboratory processed and reported 85 out of 841 patient's specimens with a temperature of 21.6C. 3. The laboratory general supervisor confirmed during interview on November 03,2023 at 1:26 PM, that the laboratory processed patient's samples outside the established temperature range.</p>
D6072	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument</p>

and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on November 3,2023, at 2:00PM, it was determined that the testing personnel did not follow the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when she processed 85 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.

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 Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on November 3,2023, at 2:00PM it was determined that the director did not assure that the manufacturer's instructions regarding to the established temperature range for Mycoplasma pneumoniae test, when the laboratory processed and reported 85 out of 841 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.

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 Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and general supervisor interview on November 3,2023, at 2:00PM, it was determined that the general supervisor did not assure that the manufacturer's instructions were followed by the testing personnel regarding to temperature range for Mycoplasma pneumoniae test. Refer to D5413.