

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0667456	(X3) Date Survey Completed 01/26/2024
Name of Provider or Supplier Lab Clinico Ensenadeno	Street Address, City, State J9 Com El Batey, Bo Ensenada, Ensenada, 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 (Meridian) manufacturer's instructions, Mycoplasma pneumoniae testing records review (years 2023-2024) and general supervisor interview on January 26, 2024 at 11:00 AM, it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 152 out of 208 days of year 2023 performed mycoplasma specimens above the established temperature range. The findings include: 1. The laboratory uses ImmunoCard Mycoplasma (Meridian) to perform Mycoplasma patient's samples tests. (Reviewed on January 26, 2024 at 11:00 AM) 2. The ImmunoCard Mycoplasma (Meridian) manufacturer's instructions establish that the Mycoplasma test must be performed at room temperature between 22 C to 25 C. (Reviewed on January 26, 2024 at 11:10 AM) 3. From January 2, 2023 to December 20, 2023, the records of the Mycoplasma pneumoniae testing showed that the laboratory processed and reported 348 out of 481 patient's specimens with a temperature range above 25.0 C. (Reviewed on January 26, 2024 at 11:25 AM) 4. The general supervisor confirmed during an interview, on January 26, 2024 at 11:30 AM, that the laboratory processed patient's samples outside the established temperature range.</p>

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 (years 2023-2024) and laboratory general supervisor interview on January 26, 2024 at 11:30 AM, it was determined that the laboratory 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 348 out of 481 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 (years 2023-2024) and laboratory general supervisor interview on January 26, 2024 at 11:30 AM, 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.