

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0672862	<b>(X3) Date Survey Completed</b> 01/17/2025
<b>Name of Provider or Supplier</b> Lab Clinico Fernando Montilla Inc	<b>Street Address, City, State</b> 401 Fernando Montilla Street, 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>D0000</b>	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clinico Fernando Montilla on January 17, 2025 by the Puerto Rico State Agency. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey on January 17, 2025.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 manufacturer's instructions, Mycoplasma pneumoniae testing record review (years 2023-2024), and laboratory director interview on January 17, 2025 at 11:00 A.M., it was determined that the laboratory failed to follow the manufacturer's instruction regarding to the established temperature range for Mycoplasma pneumoniae when 756 out of 854 patient's specimens were processed and reported for Mycoplasma pneumoniae from January 2, 2024, to December 21, 2024. The findings include: 1. The laboratory uses the ImmunoCard Mycoplasma Test Kit to perform the Mycoplasma pneumoniae qualitative tests. (Reviewed on January 17, 2025 at 11:00 A.M.) 2. On January 17, 2025 at 11:10 A.M., the ImmunoCard Mycoplasma manufacturer's instructions were reviewed. The manufacturer's instructions established to perform the Mycoplasma pneumoniae test</p>

	<p>procedures between 22C to 25 range temperature. 3. On January 17, 2025 at 11:15 A.M., the Mycoplasma pneumoniae testing records review showed that the laboratory processed and reported 756 out of 854 patient specimens for Mycoplasma pneumoniae test from January 2, 2024 to December 21, 2024, with a temperature range within 20.0C to 20.7C and 25.1C to 29.2C. 4. The laboratory director confirmed during interview on January 17, 2025, at 11:30 A.M., that the laboratory processed patient's samples outside the established temperature range by manufacturer.</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and laboratory director interview on January 17, 2025 at 9:00 AM, it was determined that the laboratory did not evaluate that the performance specifications of the Clinitek 500 (urinalysis system), Sysmex XS800i (hematology system), ASI Rapid Plasma Reagin (RPR) Card Test (syphilis serology) and Immunocard Mycoplasma (general immunology), were affected or not after the relocalization of the laboratory on January 7, 2025. The findings include: 1. On January 7, 2025, the laboratory was relocated from: Fernando Montilla 401, Hato Rey, PR to Fernando Montilla 403, Hato Rey, PR. (Reviewed on January 17, 2025, at 9:00 AM) 2. During interview with the laboratory director the evaluation of the established performance specifications were requested. The laboratory director stated that no verification was performed after the relocalization. 3. The laboratory processed and reported ninety-four (94) urinalysis patients sample, one hundred fifty one (151) complete blood count patients sample, twelve (12) RPR patients sample and thirty four (34) Mycoplasma patients sample from January 7, 2025 to January 16, 2025.</p>
<p><b>D6068</b></p>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425</p> <p>The testing personnel are responsible for specimen processing, test performance, and for reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on lack records and laboratory director interview on January 17, 2025, at 01:00 PM, it was determined that the laboratory director did not assure that the performance specification of the test system were not affected after the laboratory relocalization. Refer to: D5421.</p>
<p><b>D6093</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established</p>

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:

A .Based on Mycoplasma pneumoniae manufacturer's instructions, Mycoplasma pneumoniae testing records and laboratory director interview on January 17, 2025, at 1:00 P.M., 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 were followed. 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 laboratory technical supervisor interview on January 17, 2025, at 1:00 P.M., 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.

**D6177**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1495(b)(3)

(b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument 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 laboratory director interview on January 17, 2025, at 1:00 P.M., 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 he processed 756 out of 854 patient's specimens for Mycoplasma pneumoniae. Refer to D5413.