

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1085492	(X3) Date Survey Completed 10/19/2022
Name of Provider or Supplier Laboratorio Clinico Central Naranjito Psc	Street Address, City, State Centro Comercial El Mercado Plaza 7, Naranjito, 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 manufacturer's instructions, general immunology quality control records review (in years 2021-2022) and laboratory testing personnel interview at 11:00 AM on October 19, 2022, it was determined that the laboratory failed to perform Mycoplasma test as required by manufacturer's instructions by Meridian Immunocard Method. The findings include: 1. The laboratory use Immunocard (Meridian) Method to perform Mycoplasma patient' s samples test. 2. The manufacturer's establishes that the Mycoplasma test must be performed at room temperature between 22C to 25C reviewed at 10:30 AM. 3. Review of general immunology records from July 2021 ro October 2022, the records showed that the laboratory processed and reported eighteen (18) Mycoplasma patient's samples tests that was performed at temperatures above of range in the following nine (9) days reviewed at 10:45 AM. Date Temp. #samples 2/24 /2022 26C 1 5/10/2022 26C 4 6/6/2022 26C 4 7/18/2022 26C 3 8/8/2022 26C 1 8/15 /2022 26C 1 8/16/2022 26C 1 8/29/2022 26C 2 10/3/2022 26C 1 4. The laboratory processed and reported eighteen (18) Mycoplasma patient's samples those days reviewed 10:45 AM. 5. The laboratory testing personnel confirmed on October 19, 2022 that the laboratory performed Mycoplasma patient's samples tests above the temperature range established by the manufacturer's those days.</p>

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on ImmunoCard Mycoplasma manufacturer's instructions, general immunology (Mycoplasma) quality control reviewed from July 2021 to October 2022 and laboratory testing personnel interview on October 19, 2022 at 11:00 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instructions for monitor and documented the room temperature when tested for Mycoplasma by ImmunoCard (Meridian) Method. The finding includes: 1. The laboratory did not follow the manufacturer's instructions for monitor and documented the room temperature from July 2021 to October 2022 when patient;s specimens were tested for Mycoplasma by ImmunoCard (Meridian) Method. Refer to D5413.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's 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 ImmunoCard Mycoplasma manufacturer's instructions, general immunology (Mycoplasma) quality control reviewed from July 2021 to October 2022 and laboratory testing personnel interview on October 19, 2022 at 11:00 AM, it was determined that the laboratory testing personnel failed to follow the manufacturer's instructions for monitor and documented the room temperature when tested for Mycoplasma by ImmunoCard (Meridian) Method. The finding includes: 1. The laboratory did not follow the manufacturer's instructions for monitor and documented the room temperature from July 2021 to October 2022 when patient;s specimens were tested for Mycoplasma by ImmunoCard (Meridian) Method. Refer to D5413.