

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0982567	(X3) Date Survey Completed 04/19/2022
Name of Provider or Supplier Laboratorio Clinico Y Bacteriologico Licer	Street Address, City, State 216 Calle Munoz Rivera Plaza Buxo Suite #2, San Lorenzo, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing record, bacteriology patient records review and laboratory director interview, it was determined that the laboratory failed to enroll in an Human Health Services (HHS) approved Proficiency Testing Program for the following bacteriology tests results: urine Growth or No Growth cultures tests (Non-waived method) 1,969 out of 1,969 patients urine cultures were processed and reported from January 3, 2021 to April 18, 2022. The findings include: 1. On April 19, 2022 at 9:38 AM, the laboratory did not have records of Proficiency testing results for the following bacteriology tests results: urine Growth or No Growth cultures tests (Non-waived method) from January 3, 2021 to April 18, 2022. 2. The laboratory director confirmed on April 19, 2021 at 9:52 AM, that the laboratory did not enroll nor participate in an HHS approved Proficiency Testing Program for those tests since January 3, 2021. She stated that the laboratory establishes a comparison protocol to verify twice a year those tests. 3. The laboratory processed and reported 1,969 out of 1,969 patients urine cultures patients specimens for urine growth or no growth cultures tests from January 3, 2021 to April 19, 2022.</p>

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from January 21, 2022 to February 15, 2022 and laboratory director interview, it was determined that the laboratory failed to follow the manufacturer's instruction when 17 out of 20 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from January 21, 2022 to February 15, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On April 19, 2022 at 11:05 AM, the Mycoplasma testing records showed that the laboratory monitor and record the room temperature below 22C when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method on January 24, 2022 (two (2) patient's), January 25, 2022 (two (2) patients), January 26, 2022 (one (1) patient), January 27, 2022 (two (2) patient's), January 28, 2022 (three (3) patient's), February 1, 2022 (two (2) patient's), February 2, 2022 (one (1) patient), February 4, 2022 (one (1) patient), February 10, 2022 (two (2) patient's), February 15, 2022 (one (1) patient). 3. The laboratory director confirmed on April 19, 2022 at 11:22 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 17 out of 20 patients specimens for mycoplasma test by Immuno Card Meridian method from January 21, 2022 to February 15, 2022.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(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: (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.

This STANDARD is not met as evidenced by:
 Based on bacteriology procedures manual, bacteriology quality control records review from January 3, 2022 to April 18, 2022 and laboratory director interview, it was determined that the laboratory failed to monitor and document the bacteriology room temperature, relative humidity, voltage, refrigerator and freezer temperatures and incubator temperature from January 3, 2022 to April 18, 2022. The findings include:
 1. The bacteriology procedures manual establishes that the laboratory monitor and document daily the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and incubator temperature. 2. On April 19, 2022 at 11:35 AM, the bacteriology quality control records showed that the laboratory failed to monitor and record the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and incubator temperature from January 3, 2022 to April 18, 2022. 3. The laboratory director confirmed on April 19, 2022 at 11:46 AM, that the laboratory did not monitor and document the room temperature, relative humidity, voltage, refrigerator and freezer temperatures and incubator temperature from January 3, 2022 to April 18, 2022. 4. The laboratory processed and reported 615 patient's tests for bacteriology Growth and No Growth from January 3, 2022 to April 18, 2022.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on lack of Proficiency testing record, bacteriology patient records review and laboratory director interview on April 19, 2022 at 9:52 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the following bacteriology tests results: urine Growth or No Growth cultures (Non-waived method) from January 3, 2021 to April 19, 2022.. The finding includes: a. The laboratory director did not comply with the requirement of Proficiency testing for the following bacteriology tests results: urine Growth or No growth cultures tests (Non-waived method) from January 3, 2021 to April 19, 2022. Refer to D 6015. 2. Based on quality control records review and laboratory director interview on April 19, 2022 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the following requirements for analytic system: a. to ensure monitor and record the correct room temperature (22C - 25C) when performed Mycoplasma pneumoniae when patient's specimens were tested for Mycoplasma pneumoniae by Immuno Card Meridian from January 21, 2022 to February 15, 2022 (17 out of 20 patients specimens for mycoplasma test by Immuno Card Meridian method). b. did not assure that the laboratory monitor and document the laboratory's room temperature, relative humidity, voltage and refrigerator and freezer temperatures and incubator temperature. Refer to D6020.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on lack of Proficiency testing record, bacteriology patient records review and laboratory director interview on April 19, 2022 at 9:38 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the following bacteriology tests results: urine Growth or No Growth cultures tests (Non-waived method) from January 3, 2021 to April 19, 2022. The finding includes: 1. The laboratory processed and reported patients specimens for the following bacteriology tests results: urine No Growth or Growth cultures (Non-waived method) from January 3, 2021 to April 19, 2022. However, the laboratory was not enrolled in an HHS-approved proficiency testing program for this tests. Refer to D2000.

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:

1. Based on Mycoplasma pneumoniae quality control records review from January 21, 2022 to February 15, 2022 and laboratory director interview on April 19, 2022 at 11:32 AM, it was determined that the laboratory director failed to ensure monitor and record the room temperature (22C - 25C) when patient's specimens were tested for Mycoplasma by Immuno Card Meridian from January 21, 2022 to February 15, 2022. The finding includes: a. The laboratory director failed to ensure monitor and record the correct room temperature (22C - 25C) when performed Mycoplasma pneumoniae when patient's specimens were tested for Mycoplasma pneumoniae by Immuno Card Meridian from January 21, 2022 to February 15, 2022 (17 out of 20 patients specimens for mycoplasma test by Immuno Card Meridian method). Refer to D5403.
2. Based on bacteriology quality control records review from January 3, 2022 to April 18, 2022 and laboratory director interview on April 19, 2022 at 11:46 AM, it was determined that laboratory director failed to ensure compliance with the requirements establishes on the bacteriology procedures manual. The finding includes: a. The laboratory director did not assure that the laboratory monitor and document the laboratory's room temperature, relative humidity, voltage and refrigerator and freezer temperatures and incubator temperature. Refer to D5413.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

1. Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from January 21, 2022 to February 15, 2022 and laboratory director interview on April 19, 2022 at 11:31 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's were tested for Mycoplasma by Immuno Card Meridian Method. The finding includes: a. The laboratory testing personnel did not follow the manufacturer's instruction for monitor and documented the room temperature (22C - 25C) from January 21, 2022 to February 15, 2022 when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5403. 2. Based on bacteriology quality control records review from January 3, 2022 to April 18, 2022 and laboratory director interview on April 19, 2022 at 11:46 AM, it was determined that laboratory testing personnel failed to ensure compliance with the requirements establishes on the bacteriology procedures manual. The finding includes: a. The laboratory testing personnel did not assure that the laboratory monitor and document the laboratory's room temperature, relative humidity, voltage and refrigerator and freezer temperatures and incubator temperature. Refer to D5413.