

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0657994	(X3) Date Survey Completed 03/20/2019
Name of Provider or Supplier Lab Clinico Toledo	Street Address, City, State Calle Palma 51, Arecibo, 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
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on bacteriology quality control records review from year 2018 to 2019 and interview with the bacteriology supervisor and laboratory director on March 20, 2019 at 2:00 P.M. it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. The finding includes: 1. The laboratory failed to check each day of testing the antimicrobial susceptibility tests . Refer to D5507. 2. The laboratory did not take nor document any correction action when the incubator temperature was out of range. Refer to D5781.</p>
D5507	<p>BACTERIOLOGY CFR(s): 493.1261(b)(c)</p> <p>(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on bacteriology quality control records review, and bacteriology technical supervisor interview at 2:00 P.M. on March 20, 2019 , it was determined that the laboratory failed to check each day of testing the antimicrobial susceptibility tests . The findings include: 1. The laboratory begin to use the Microscan DxM 1096 system on February 12, 2019. 2. The bacteriology quality controls records (antimicrobial susceptibility tets) showed that the laboratory did not check each day of testing the antimicrobial susceptibility tests when specimens antimicrobial susceptibility were tested from February 12, 2019 to March 19, 2019. 3. The laboratory performed and reported 3.000 patients specimens antimicrobial susceptibility tests for gram negative organism and for gram positive organism since February 12, 2019. 4. The laboratory performed weekly the antimicrobial susceptibility tests quality control procedures. 5. The bacteriology technical supervisor confirmed on March 20, 2019 at 2:00 P.M., that the laboratory did not check each day of testing the antimicrobial susceptibility tests.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on bacteriology preventive maintenance records review (year 2018-2019) and bacteriology technical supervisor interview on March 20, 2019 at 10:25 A.M., it was determined that the laboratory did not take nor document any correction action when the incubator temperature was out of range. The findings include: 1. The laboratory had in use at the bacteriology area six incubator (incubator # 1, #2, #3, #4, #5, and #6). 2. The bacteriology preventive maintenance log sheet showed that the incubator temperature range must be between 35 C -37 C. 3. Review on bacteriology incubator temperature log sheet (Incubator # 3 and # 6) from January 2019 to February 2019 , showed that the incubator was out of range. 4. The temperature records from the incubator # 3 (urine culture), showed the following: a. January 2019 - 13 of 27 days showed that the temperature was below 35 C. b. February 2019- 14 of 24 days showed that the temperature was below 35 C. 5. The temperature records from the incubator # 6 (candle jar) , showed the following: a. January 2019 - 6 of 26 days showed that the temperature was below 35 C. b. February 2019- 2 of 24 days showed that the temperature was below 35 C. 6. The laboratory incubated 100 urine culture samples in the incubator # 3 and 2000 patient samples in the incubator # 6 (candle jar) 7. The bacteriology technical supervisor confirmed on March 20, 2019 at 10:25 A. M., that the temperature of the incubator # 3 and 6 was out of range and the laboratory did not perform nor document remedial actions those days.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.

1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on Bacteriology quality control records review (2018-2019) bacteriology supervisor and laboratory director interview on March 20, 2019 at 2:00 P.M. it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the bacteriology quality control requirements. The finding includes: 1. The laboratory director did not comply with the requirement for bacteriology analytical systems requirements. Refer to D 6093.

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 review of bacteriology quality control records (2018-2019) and interview with the bacteriology supervisor and laboratory director on March 20, 2019, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D 5507 and D 5781.

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 bacteriology quality control records review in 2018-2019 and laboratory director interview on March 20, 2019 at 200 P.M. it was determined that the general supervisor failed to follow quality control procedures. Refer to D5507 and D5781.

D6177

TESTING PERSONNEL RESPONSIBILITIES

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

Each individual performing high 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 bacteriology quality control records review from year 2018 to 2019 and bacteriology technical supervisor interview March 20, 2019 at 11:00 A.M., it was determined that testing personnel failed to follow quality control requirements for bacteriology tests. The findings include: 1. The laboratory failed to check each day of

testing the antimicrobial susceptibility tests . Refer to D5507. 2. The laboratory did not take nor document any correction action when the incubator temperature was out of range. Refer to D5781.