

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658103	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Laboratorio Clinico Hormigueros	Street Address, City, State Luis Munoz Marin Avenue # 3, Hormigueros, 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 (2022-2023) and interview with the laboratory testing personnel, laboratory general supervisor and laboraory director on September 7, 2023 ay 1:00 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. Refer to D5507 (the laboratory did not perform quality control procedures for susceptibility tests each day of testing).</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: Based on bacteriology quality control records review , testing personnel and</p>

laboratory director interview on September 8, 2023 at 12:30 P.M. , it was determined that the laboratory failed to check each day of testing with the appropriate control organisms the antimicrobial susceptibility tests were performed. The findings include: 1. The bacteriology quality control records showed on September 8, 2023 at 12: 30 P. M.that the laboratory did not check with the appropriate control organisms the antimicrobial susceptibility tests when patients specimens antimicrobial susceptibility were tested from may 2023 to august 2023. 2. The laboratory performed and reported 12 patients specimens antimicrobial susceptibility tests for gram negative organism and 2 patients specimens antimicrobial susceptibility tests for gram positive organism. 3. The testing personnel stated on september 8, 2023 at 12:40 P.M. , that the laboratory did not check daily the susceptibility tests. She stated that the laboratory checked monthly the susceptibility tests quality control procedures.

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 room temperature area records review (2022-2023) and laboratory director on September 7, 2023 at 12:00 P.M., it was determined that the laboratory did not take nor document any correction action when the room temperature was out of the establishes range. The findings include: 1. The laboratory Bacteriology room temperature area log sheet establishes that the laboratory must monitor and document the room temperature daily. The range must be between 18 C-26 C. 2. Review on Bacteriology room temperature log sheet records from January 1, 2023 to September 6,2023. 3. Bacteriology area temperature were below 18C the following days : 7/15, 7/19, 7/20, 7/27, 7/28, 7/29, 8/1, 8/2, 8/3, 8/4, 8/5, 8/7, 8/9/, 8 /11, 8/12, 8/16, 8/21, 8/22, 8/24, 8/26, 8/28, 8/29, 8/30, 8/31, 9/2, 9/4/2023. 4. The laboratory testing personnel and laboratory director confirmed on September 7, 203 at 12:30 P.M. that the laboratory did not perform nor document remedial actions when the Bacteriology room temperature was out of range 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 (year 2022-2023) and laboratory director interview on September 7, 2023 at 1:10 A.M , it was determined

that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the Bacteriology quality control 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 (2022-2023) and interview with the laboratory testing personnel and laboratory director on September 7, 2023 at 1: 00 P.M. it was found that the laboratory director failed to ensure compliance with the requirement for analytic systems. The findings include: 1. The laboratory failed to check each day of testing with the appropriate control organisms the antimicrobial susceptibility tests were performed. Refer to D5507. 2.The laboratory did not take nor document any correction action when the room temperature in Bacteriology area was out of the establishes range. Refer to 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 review of bacteriology quality control records, interview with the laboratory testing personnel and laboratory director on September 7, 2023 at 1: 00 P.M. it was found that the laboratory testing personnel failed to follow Bacteriology quality control procedures. The findings include: 1. The laboratory failed to check each day of testing with the appropriate control organisms the antimicrobial susceptibility tests were performed. Refer to D5507. 2.The laboratory did not take nor document any correction action when the room temperature in Bacteriology area was out of the establishes range. Refer to D5781.