

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658059	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier Lab Clinico Hospital General Castaner	Street Address, City, State Road #135 Rm 642, Castaner, 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 and interview with the laboratory technical on April 9, 2019 at 11:15 AM., it was determined that the laboratory did not have specific written instructions for blood cultures and also did not ensure that the testing personnel followed the written instructions for blood culture procedures. Refer to D5401.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: 1. Based on review of the bacteriology written procedures manual, hand written instructions for blood cultures, blood culture worksheet review and interview with the laboratory technical supervisor and testing personnel on April 9, 2019 at 11:15 AM, it was found that three different non-automated blood cultures written instructions were available to the testing personnel. The findings include: a. The laboratory technical supervisor state on April 9, 2019 at 11:15 AM stated that the Bac- T- Alert system</p>

was out of service since March 21, 2019. She also stated that in the meanwhile they performed a non-automated incubation process. b. Three different written instructions were reviewed: one included in the bacteriology procedure manual and two others posted in the bacteriology area. c. The written instruction included in the procedure manual showed the following: * To incubate the bottles at 37 C for eight days * At 24 hours sub-culture the aerobic and anaerobic bottles to blood and chocolate agar * AT 48 hours observed the culture plates and performed a preliminary report. * At the seventh days sub-culture again aerobic and anaerobic bottles to blood and chocolate agar d. One of the hand written instruction observed at the bacteriology area showed the following: *At 24 hours cub-culture the aerobic and anaerobic bottles to blood, chocolate and Mac Conkey agar. At the next 24 observed the aerobic sub-cultures At 48 hours observed the anaerobic sub-cultures * At the seventh day sub-culture the anaerobic bottles again and observed within 24 hours. * AT the eighth day sub-culture the aerobic bottle and observed at 24 hours. e. The other hand written instructions showed the following: "Instrument out of service" Protocol: *Aerobic- within 24 hours perform a gram satin and sub-culture to blood, chocolate and Mac Conkey agar. *Anaerobic - The same procedure within 48 hours * For the next 10 days check for turbidity. * At the tenth day, sub-culture to blood, chocolate and Mac Conkey agar. f. The technical supervisor stated that the instructions given by her were the third ones (Item #5), however the testing personnel # 6 stated that the instructions that were being followed by all the testing personnel were the second ones (Item # 4), the instructions were written by testing personnel # 1. 2. Based on interview with the laboratory technical supervisor, the testing personnel # 6 and review of the worksheets designed for blood cultures documentation and observation, it was found that the testing personnel did not follow the written instructions. The findings include: a. Testing personnel # 6 stated on March 9, 2019 at 11:50 AM, that the instructions that were being followed by all the testing personnel were the following: *At 24 hours cub-culture the aerobic and anaerobic bottles to blood, chocolate and Mac Conkey agar. * At the next 24 observed the aerobic sub-cultures * At 48 hours observed the anaerobic sub-cultures * At the seventh day sub-culture the anaerobic bottles again and observed within 48 hours. * At the eighth day sub-culture the aerobic bottle and observed at 24 hours. b. During interview the technical supervisor also stated that since March 21, 2019 a new worksheet was designed. Review of the worksheet showed that for blood cultures the following procedures must be documented: * At 24 hours- subculture in blood agar the aerobic and anaerobic bottle, reading of the aerobic plate in the next 24 hours and the anaerobic one at 48 hours. Document a preliminary report. * At the seventh day sub-culture the anaerobic bottle - read at 48 hours * At the eighth day sub-culture of the aerobic bottle- read at 24 hours c. Review of patient's blood cultures worksheets showed the following: i. Patient identification - 35492-sample collection March 31, 2019. Reported as no growth as on April 8, 2019. As per written instructions the final test report must be performed on April 9, 2019. Not on April 8, 2018. ii. Patient identification - 05803-sample collection March 28, 2019. Review of the worksheets showed that the preliminary report was not performed. d. At 12:20 PM, inside the bacteriology incubator three sets of blood cultures bottles were observed. The sample collection date was April 7, 2019. By the day survey (March 9, 2019) no sub-cultures were performed. e. The technical supervisor stated that she was not aware of the situation.

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 blood cultures written instructions and laboratory technical supervisor interview on April 9, 2019 at 12:15 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the blood cultures analytic procedures. Refer to D6087 and D6106.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on review of blood cultures worksheets and interview with the technical supervisor, it was determined that the laboratory director did not make sure that the blood cultures testing procedures were followed by the testing personnel. The findings include: a. The testing personnel completed a blood culture procedure before the established due date of nine days after sample collection. b. The testing personnel did not followed written instructions regarding sub-cultures procedures. Refer to D 5401 - finding #2

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on bacteriology manual, hand written instructions for blood cultures review and interview with the technical supervisor on April 9, 2019 at 11:15 AM, it was found that the laboratory director did not sign not approved the written procedures for bacteriology blood cultures. The findings include: a. At the date of survey three different written procedures were available for blood cultures. b. None of the procedures was approved by the laboratory director. c. The technical supervisor stated that the procedure included the bacteriology procedures manual was under revision, and the other two were written by her and by testing personnel #1. Refer to D 5401- Finding #1

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high 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:
Based on review of the written instructions that were being used by the testing

personnel for blood cultures and interview with the laboratory technical supervisor on April 9, 2019 at 11:15 AM, it was found that the testing personnel did not follow the written instructions when they performed patient's blood cultures. Refer to D5401, finding #2.