Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0982567	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Y Bacteriologico Licer	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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on lack of Proficiency testing record for bacteriology tests, bacteriology testing records review and laboratory technical supervisor interview on April 5, 2018 at 9:10 AM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Bacteriology growth or no growth organisms results when it processed 4009 out of 4009 patients cultures specimens cultures from January 2016 to April 4, 2018. The findings include: 1. The Proficiency testing showed no records for bacteriology tests from January 2016 to April 4, 2018. 2. On April 5, 2018 at 9:10 AM, the bacteriology testing record showed that the laboratory performed the primary inoculation in patients cultures specimens since January 2016. During years 2016 processed nasal, throat and urine cultures, during year 2017 processed urine cultures and in the current year 2018 processed nasal, throat and urine cultures. The laboratory reported no growth and colony count results and referred cultures to another laboratory for organisms identification and susceptibility tests. 3. The technical supervisor confirmed on April 5, 2018 at 9:20 AM, that the laboratory performed the primary inoculation for the patients cultures specimens, reported no growth and colony count results and referred cultures to another laboratory for

	organisms identification and susceptibility tests since January 2016. She also confirmed that the laboratory did not enroll and participate in an HHS approved Proficiency Testing Program for those tests; instead the laboratory performed a comparison procedures since April 2016. 3. The laboratory performed the primary inoculation for the following patients cultures specimens from January 2016 to April 4, 2018: a. 2,502 patients cultures specimens during year 2016. b. 1,126 patients cultures specimens during year 2017. c. 381 patients cultures specimens for the current year 2018.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory technical supervisor interview on April 5, 2018 at 8:30 AM, it was determined that the laboratory failed to follow the established schedule for the technical supervisor competence evaluation. The findings include: a. The laboratory schedule for the technical supervisor competence evaluation showed that it must be performed every year. b. The laboratory did not perform the technical supervisor competence evaluations since February 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review, personnel records review and laboratory technical supervisor interview on April 5, 2018 at 8:30 AM, it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate yearly the requirements for the technical supervisor competence. Refer to D 5209.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of validation records of the Mindray system for complete cell count (CBC) test and technical supervisor interview on April 5, 2018 at 9:28 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new instruments on April 27, 2017 before reporting 2861 out of 2861 CBC tests results from October 2017 to April 4, 2018. The findings include: 1. On April 5, 2018 at 9:28 AM, the Mindray system validation records showed that the laboratory laboratory performed the validation procedures on April 27, 2017 and it did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The technical supervisor confirmed on April 5, 2018 at 9:38 AM, that the laboratory did not verify that the Mindray system manufacturer's reference intervals (normal values) when it validated the system on on April 27, 2017. She stated that the laboratory processed and reported the CBC patients specimens by the Mindray system since October 13, 2017 and the laboratory included in the Mindray system CBC reports the reference intervals of the former laboratory CBC tests analyzer (Excell 2280 system). 4. The laboratory processed and reported 2861 out of 2861 CBC patients specimens by the Mindray system from October 2017 to April 4, 2018: 198 CBC in October 2017, 361 CBC in November 2017, 385 CBC in December 2017, 728 in January 2018, 476 CBC in February 2018, 630 CBC in March 2018 and 83 CBC from April 1 to April 4, 2018.
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 lack of Proficiency testing record for bacteriology tests, bacteriology testing records review, review of validation records of the Mindray system for complete cell count (CBC) test and technical supervisor interview on April 5, 2018 at 9:28 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Proficncy Testing Program for bacteriology requirements and with the analytical system requirements for the CBC tests. The findings include: 1. The laboratory director did not comply with the Proficncy Testing Ptogram for bacteriology. Refer to D 6088. 2. The laboratory director did not comply with the analytical systems requirements for CBC tests. Refer to D 6093.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must 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 for bacteriology tests, bacteriology testing records review and laboratory technical supervisor interview on April 5, 2018 at 9:10 AM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for Bacteriology growth or no growth organisms results when it processed 4009 out of 4009 patients cultures

	specimens cultures from January 2016 to April 4, 2018. The finding includes: 1. The laboratory processed and reported patients cultures specimens for growth or no growth and colony count results from January 2016 to April 4, 2018. However, the laboratory is not enroll in a an HHS-approved proficiency testing program for those tests. Refer to D 2000.
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 validation records of the Mindray system for complete cell count (CBC) test and technical supervisor interview on April 5, 2018 at 9:28 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for the CBC tests when the laboratory processed and reported 2861 out of 2861 CBC tests by the Mindray system results from October 2017 to April 4, 2018. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirements of the CBC tests from October 2017 to April 4, 2018. Refer to D 5421. (The laboratory did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population .follow before reporting 2861 out of 2861 CBC tests results by the Mindray system from October 2017 to April 4, 2018.)
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of validation records of the Mindray system for complete cell count (CBC) test and technical supervisor interview on April 5, 2018 at 9:28 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems of the CBC tests from October 2017 to April 4, 2018. Refer to D 5421. (The laboratory did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population .follow before reporting 2861 out of 2861 CBC tests results by the Mindray system from October 2017 to April 4, 2018.)