Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0945814	11/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Montellano	Carr 14 Km 72 Hm 3, Cayey, 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
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: 1. Based on review of validation records of the DxC 700au system and technical supervisor interview at 10:50 am on November 8, 2019, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 81,107 routine chemistry patient tests results from May 1, 2019 to November 7, 2019. The findings included: a. On November 8, 2019 at 10:50 AM, the validation records of the DxC 700au system showed that the laboratory performed the validation procedures on April 24, 2019. However, the laboratory did not verify that the manufacturer's normal values of the routine chemistry tests are appropriate for the laboratory's patient population before reporting patient results from May 1, 2019 to November 7, 2019. b. The supervisor interview confirmed at 10:50 am on November 8, 2019 , that the laboratory did not verify that the manufacturer's reference intervals (normal values) before reporting routine chemistry patients tests results. c. The laboratory processed and reported 81,107 routine chemistry tests from May 1, 2019 to November 7, 2019 by the DxC 700au system. 2. Based on review of validation records of the Act 5 Diff system and technical supervisor interview at 11:10 am on November 8, 2019, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before

	reporting complete blood cell (CBC) patient results during year 2018. The findings included: a. On November 8, 2019 at 11:10 AM, the validation records of the Act 5 diff system showed that the laboratory performed the validation procedures on December 6, 2017. However, the laboratory did not verify that the manufacturer's normal values of the CBC tests are appropriate for the laboratory's patient population before reporting 40,696 CBC tests results during year 2018. b. The supervisor interview confirmed at 11:10 am on November 8, 2019, that the laboratory did not verify that the manufacturer's reference intervals (normal values) before reporting patients CBC results. c. The laboratory processed and reported 40,696 CBC tests during year 2018.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Individualized Quality Control Plan (IQCP) in Bacteriology and interview with the technical supervisor at 12:40 PM on November 8, 2019, the laboratory failed to develop complete IQCP for the Microscan Identification system and Antimicrobial Sensitivity test. The findings include: 1. The IQCP for the Microscan Identification system and Antimicrobial Sensitivity test did not include the following requirements: a. The Risk Assessment (RA) information (potential failure modes, possible failure cause, estimate the probability that the failures would occur and estimate the probability would lead to a hazardous situation). b. The Quality Control Plan (QCP) did not have the approval signature of the laboratory director. c. The Quality Assessment (QA) section was not included. 2. The technical supervisor confirmed at 12:40 PM on November 8, 2019, the laboratory failed to develop complete IQCP for the Microscan Identification system and Antimicrobial Sensitivity test. 3. The laboratory processed 1,336 patients specimens in the Bacteriology area during the year 2018.
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 Individualized Quality Control Plan (IQCP) in Bacteriology, validation records of the DxC 700au system and the Act 5 Diff system, and interview with the technical supervisor at 12:40 PM on November 8, 2019, the laboratory director failed to comply with requirements of the quality control programs in the

	following specialties: Bacteriology, Routine chemistry and Hematology. Refer to D 5421 (1) (2) (The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting routine chemistry and CBC patient results). Refer to D 5445 (The laboratory failed to develop complete IQCP for the Microscan Identification system and Antimicrobial Sensitivity test).
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 DxC 700au system and the Act 5 Diff system, and interview with the technical supervisor at 11:10 AM on November 8, 2019, the technical superviosr failed to comply with the requirements for analytic systems. Refer to D 5421 (1) (2) (The laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting routine chemistry and CBC patient results).