Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658037	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Borinquen	Calle Dr Goyco Esq Baldorioty, Caguas, 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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, Nova Lite ANA Plus manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), testing record (year 2019) for anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GAP) quantitative tests, procedures manual for ANA quantitative tests, validation records of Immuno Concepts ANA HEp-2000 and Nova Lite ANA Plus quantitative tests, interview with the technical supervisor and testing personnel in charge of the ANA quantitative tests on June 4, 2019 at 2:30 PM, it was determined that the laboratory failed to meet the requirements of the General Immunology (Ana, AMA, ASMA and GPA quantitative tests). Refer to D 5405 (1) (The laboratory failed to follow manufacturer's instructions when 308 out of 3,913 patients specimens were processed and reported for ANA quantitative tests from January 1, 2018 to May 31, 2019). Refer to D 5405 (2) (The laboratory failed to follow manufacturer's instructions when 34 out of 231 patients specimens were processed and reported for AMA, ASMA and GAP quantitative tests from January 6, 2019 to June 3, 2019). Refer to D5421 (The laboratory failed to complete the evaluation of the performance specification of the following quantitative tests since May 2013: ANA, AMA, ASMA and GPA.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when

applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:
1. Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), procedures manual review and interview with the testing personnel in charge of the ANA quantitative tests on June 4, 2019 at 12:00 PM, it was determined that the laboratory failed to follow manufacturer's instructions when 308 out of 3,913 patients specimens were processed and reported for ANA quantitative tests from January 1, 2018 to May 31, 2019. The findings included: a. The laboratory performed the ANA quantitative tests by Immuno Concepts ANA HEp-2000 method to determined quantitative ANA pattern detection in patients specimens from January 1, 2018 to May 31, 2019. b. The Immuno Concepts ANA HEp-2000 manufacturer instructed the laboratory to dilute patient sample at the following serial dilutions: 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280 to 1:2560. Also, the manufacturer establish that the tittering results should be reported as the last serial dilution in which clearly discernible pattern staining is seen. Results with strong reaction at 1:2560 dilution should be reported as greater than 1:2560. c. The laboratory procedures manual includes the Immuno Concepts ANA HEp-2000 manufacturer instructions for the processing and reporting of the ANA quantitative tests. d. Review of the ANA quantitative testing records, on June 4, 2019 at 12:00 PM, showed that the laboratory did not perform the dilution beyond the 1:1280 dilution, even in those patient's specimens reported with positive ANA pattern detection at 1:1280 from January 1, 2018 to May 31, 2019. e. The testing personnel in charge of the ANA quantitative tests confirmed on June 4, 2019 at 12:00 PM, that the laboratory did not perform the patients specimens dilution beyond the dilution 1:1280 for the ANA quantitative tests from January 1, 2018 to May 31, 2019. She stated that the laboratory performed the dilutions of the ANA quantitative patients specimens by the AFT 2000 system. f. The laboratory processed and reported 308 patients specimens with with positive results of ANA pattern detection at 1:1280 from January 1, 2018 to May 31, 2019. g. The laboratory did not perform the 1:2560 dilution. 2. Based on Nova Lite ANA Plus manufacturer's instruction, testing record (year 2019) for anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GAP) quantitative tests and interview with the testing personnel in charge for the quantitative tests on June 4, 2019 at 1:40 PM, it was determined that the laboratory failed to follow manufacturer's instructions when 34 out of 231 patients specimens were processed and reported for AMA, ASMA and GAP quantitative tests from January 6, 2019 to June 3, 2019. The findings included: a. The laboratory performed the AMA, ASMA and GAP quantitative tests by Nova Lite ANA Plus method from January 6, 2019 to June 3, 2019. b. The Nova Lite ANA Plus manufacturer instructed the laboratory to dilute patient sample with an initial dilution of 1:20 and make serial 2-fold dilutions from the initial dilution for all positive samples (i.e. 1:40, 1:80, ...1:5120). c. On June 4, 2019 at 1:40 PM, review of the testing records of the AMA, ASMA and GPC quantitative tests showed that the laboratory did not perform the dilution beyond the dilution 1:1280 even in those in 3 out of 3 patients specimens reported with positive results of GPC pattern detection at 1:1280 from January 6, 2019 to May 31, 2019. d. Also, the testing records of the AMA, ASMA and GPC quantitative tests showed that the laboratory did not document the results of the serial dilutions for the 34 patients samples processed and reported with positive results from January 6, 2019 to May 31, 2019. The laboratory documented in the testing records the results of the final positive dilution for each

	patients sample. e. The testing personnel confirmed on June 4, 2019 at 1:40 PM, that the laboratory did not perform the patients specimens dilution beyond the dilution 1: 1280 and stated that the laboratory performed the patients samples serial dilution manually and the laboratory only documented the result of the final positive dilution from January 6, 2019 to May 31, 2019. f. The laboratory processed and reported the following positive quantitative tests results: 5 patients specimens for AMA, 10 patients specimens ASMA and 19 patients specimens GAP from January 6, 2019 to June 3, 2019.
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 Immuno Concepts ANA HEp-2000, Immuno Concepts ANA HEp-2000 manufacturer's instruction and interview with the technical supervisor on June 4, 2019 at 2:30 PM, it was determined that the laboratory failed to complete the evaluation of the performance specification of the ANA quantitative tests since May 2013. The findings include: a. The Immuno Concepts ANA HEp-2000 manufacturer instructed the laboratory to dilute patient sample at the following serial dilutions: 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280 to 1:2560. b. On June 4, 2019 at 2:30 PM, the validation records showed that the laboratory performed the validation of the Immuno Concepts ANA HEp-2000 on May 3, 2013. However, the laboratory did not verify the method dilutions of 1:1280 and 1:2560. c. The technical supervisor confirmed on June 4, 2019 at 2:30 PM, that the laboratory did not verify those dilutions in the validation of the Immuno Concepts ANA HEp-2000. 2. Based on review of validation records of Nova Lite ANA Plus, Nova Lite ANA Plus manufacturer's instruction and interview with the technical supervisor on June 4, 2019 at 2:30 PM, it was determined that the laboratory failed to complete the evaluation of the performance specification of the following quantitative tests since May 2013: AMA, ASMA and GPA. The findings include: a. The Nova Lite ANA Plus manufacturer instructed the laboratory to dilute patient sample with an initial dilution of 1:20 and make serial 2-fold dilutions from the initial dilution (1:20) for all positive samples to 1:5120 (1:40, 1:80, ...1:5120). b. On June 4, 2019 at 2:30 PM, the validation records showed that the laboratory performed the validation of the Nova Lite ANA Plus on May 17, 2013. However, the laboratory did not verify the method dilutions of 1:640, 1:1280 , 1:2560 and 1:5120. c. The technical supervisor confirmed on June 4, 2019 at 2:30 PM, that the laboratory did not verify those dilutions in the validation of the Nova Lite ANA Plus methods.
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 Immuno Concepts ANA HEp-2000, Nova Lite ANA Plus manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GAP) quantitative tests records (year 2019), procedures manual for ANA quantitative tests, validation records of Immuno Concepts ANA HEp-2000 and Nova Lite ANA Plus quantitative tests and interview with the technical supervisor and testing personnel in charge of the ANA quantitative tests on June 4, 2019 at 2:30 PM, it was determined that the laboratory director fulfill his responsibilities and duties to ensure compliance with the requirements of the analytic system. Refer to D 6093 (The laboratory director failed to comply with the requirements of the analytic system for the ANA, AMA, ASMA and GPA quantitative tests).
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 Immuno Concepts ANA HEp-2000, Nova Lite ANA Plus manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GAP) quantitative tests records (year 2019), procedures manual for ANA quantitative tests, validation records of Immuno Concepts ANA HEp-2000 and Nova Lite ANA Plus quantitative tests and interview with the technical supervisor and testing personnel in charge of the ANA quantitative tests on June 4, 2019 at 2:30 PM, it was determined that the laboratory director failed to comply with the requirements of the analytic system for the Ana, AMA, ASMA and GPA quantitative tests. Refer to D 5014 (The laboratory failed to meet the requirements of the General Immunology (Ana, AMA, ASMA and GPA quantitative tests).
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 Immuno Concepts ANA HEp-2000, Nova Lite ANA Plus manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2018 and 2019), anti-mitochondrial (AMA), anti-smooth muscle (ASMA) and gastric parietal antibodies (GAP) quantitative tests records (year 2019), procedures manual for ANA quantitative tests, validation records of Immuno Concepts ANA HEp-2000 and Nova

	Lite ANA Plus quantitative tests and interview with the technical supervisor and testing personnel in charge of the ANA quantitative tests on June 4, 2019 at 2:30 PM,, it was determined that the technical supervisor failed to ensure compliance with the requirements of the analytic system for the ANA, AMA, ASMA and GPA quantitative tests. Refer to D 5405 (1) (The laboratory failed to follow manufacturer's instructions when 308 out of 3,913 patients specimens were processed and reported for ANA quantitative tests from January 1, 2018 to May 31, 2019). Refer to D 5405 (2) (The laboratory failed to follow manufacturer's instructions when 34 out of 231 patients specimens were processed and reported for AMA, ASMA and GAP quantitative tests from January 6, 2019 to June 3, 2019