Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1095984	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Irizarry Guasch Miradero	Carretera 108 Km 2 Hm 9 Barrio Miradero, Mayaguez, 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, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that the laboratory failed to meet the requirements of the General Immunology (ANA tests). Refer to D 5405 (The laboratory failed to follow manufacturer's instructions when 424 out of 1,078 patients specimens were processed and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019). Refer to D 5421 (The laboratory failed to complete the evaluation of the performance specifications of the ANA Hep 2000 quantitative tests since November 18, 2016). Refer to D 5429 (1) (The laboratory failed to follow written instructions for the preventive maintenance of the Image Navigator microscope when 1,078 out of 1,078 patients specimens were examined and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019).
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: Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual and interview with the general supervisor (TM#4) on March 26, 2019 at 11:50 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 424 out of 1,078 patients specimens were processed and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019. The findings included: 1. The laboratory performed the ANA quantitative tests by Immuno Concepts ANA HEp-2000 method to determine quantitative ANA pattern detection in patients specimens from June 16, 2017 to March 25, 2019. 2. 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. 3. On March 26, 2019 at 11:50 AM, the ANA quantitative testing records showed that the laboratory did not perform the dilution beyond the dilution 1:640 even in those patient's specimens reported with positive results of ANA pattern detection at 1:640 and positive results over 1:640 from June 16, 2017 to August 17, 2017. 4. The ANA quantitative testing records also showed that the laboratory did not perform the dilution beyond the dilution 1:320 even in those patient's specimens reported with positive results of ANA pattern detection at 1:320 and positive results over 1:320 from September 14, 2017 to March 25, 2019. 5. The general supervisor (TM#4) confirmed during the interview on March 26, 2019 at 11:50 AM, that the laboratory did not perform any patients specimens dilution beyond 1:640 (1:1280 and 1:2560) from June 16, 2017 to August 17, 2017 and did not perform any patients specimens dilution beyond 1:320 (1:640, 1:1280 and 1:2560) from September 14, 2017 to March 25, 2019. She stated that the laboratory performed the dilutions of the patients specimens by the AFT 2000 system. 6. The general supervisor stated on March 26, 2019 at 11:50 AM, that the laboratory examined for reactivity of the patients slides by the microscope Image Navigator and reported as following: a. From June 16, 2017 to August 17, 2017; those patients slide that showed a positive slight reactivity at 1:640 was reported positive at 1:640 and those patients slide that showed a positive strong reactivity at 1:640 was reported positive over 1:640. b. From September 14, 2017 to March 25, 2019; those patients slide that showed a positive slight reactivity at 1:320 was reported positive at 1:320 and those that showed a positive strong reactivity at 1: 320 was reported positive over 1:320. 7. The laboratory did not have the protocol for this practice. The general supervisor (TM#4) confirmed on March 26, 2019 at 11: 50AM, that the laboratory did not have written procedures for this practice. 8. The laboratory processed and reported 424 out of 1,078 patients specimens for ANA quantitative tests from June 16, 2017 to March 25, 2019: a. From June 16, 2017 to August 17, 2017, the laboratory reported 19 patients specimens positive at 1:640 and one patient specimen positive over 1:640. b. From September 14, 2017 to March 25, 2019, The laboratory reported 178 patients specimens positive at 1:320 and 226 patients specimens positive over 1:320.
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 Immuno Concepts ANA HEp-2000, Immuno Concepts ANA HEp-2000 manufacturer's instruction and interview with the general supervisor (TM#4) on March 26, 2019 at 1:00 PM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of the ANA Hep 2000 quantitative tests since November 18, 2016. The findings include: 1. T he 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. 2. The laboratory performed the validation of the Immuno Concepts ANA HEp-2000 on November 18, 2016. However, the laboratory did not verify the method dilutions of 1:1280 and 1:2560. 3. The general supervisor (TM#4) confirmed on March 26, 2019 at 1:00 PM, that the laboratory did not verify those dilutions when it validated the Immuno Concepts ANA HEp-2000 method.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the Image Navigator microscope when 1,078 out of 1,078 patients specimens were examined and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019. The findings includes: a. On March 26, 2019 at 1:20 PM, the Image Navigator Operator manual instructed the laboratory to perform a daily and monthly cleaning and maintenance procedures. b. The laboratory did not have records for the daily and monthly maintenance of the Image Navigator microscope from June 16, 2017 to March 25, 2019. c. The general supervisor (TM#4) confirmed on March 26, 2019 at 1:20 PM, that the laboratory did not have a records for the required maintenance. She stated that the preventive maintenance were performed but not recorded. d. The laboratory examines and reported 1,078 out of 1,078 patients specimens for ANA quantitative tests from June 16, 2017 to March 25, 2019 by the Image Navigator microscope. 2. Based on bacteriology quality control records (January 2, 2018 to March 26, 2019), lack of preventive maintenance records, manufacturer's instructions review and interview with the laboratory general supervisor (TM# 5) on March 26, 2019 at 10:28 AM, it was determined that the laboratory failed to follow the manufacturer's instructions for the preventive maintenance of the new Gene Xpert (Cepheid) instrument. The findings include: a. The laboratory uses a new Gene Xpert (Cepheid - serial number 808135) instrument for Chlamydia trachomatis and Neisseria gonorrhoea from May 11, 2018. b. The manufacturer unstructured a daily cleaning preventive maintenance. c. The laboratory did not perform the daily preventive maintenance of the new Gene

	Xpert from May 11, 2018 to March 26, 2019. d. The laboratory general supervisor (TM# 5) confirmed on on March 26, 2019 at 10:28 AM, that the laboratory did not perform the required preventive maintenance. e. The laboratory processed and reported 2,068 out of 2,068 patients samples for Chlamydia trachomatis and Neisseria gonorrhoea from May 11, 2018 to March 26, 2019.
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 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that laboratory director failed fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements for ANA tests. 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 Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that laboratory director failed to ensure compliance with the requirements of the analytic systems for ANA quantitative tests. Refer to D 5014 (The laboratory failed to meet the requirements of the General Immunology -ANA tests).
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by:

	Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that the laboratory technical supervisor failed to fulfill his responsibilities and duties to ensure compliance with the analytic system (ANA tests). Refer to D 5014.
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 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems (ANA tests). Refer to D 5014.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that the general supervisor (TM#4) failed to fulfill her responsibilities for the analytic system of ANA quantitative test results. Refer to D 6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

	This STANDARD is not met as evidenced by: Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quantitative testing records (years 2017, 2018 and 2019), lack of procedures manual for ANA tests, validation records of Immuno Concepts ANA HEp-2000, Image Navigator Operator manual, lack of Image Navigator preventive maintenance records and interview with the general supervisor (TM#4) on March 26, 2019 at 1:20 PM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting ANA quantitative test results. Refer to D 5405 (The laboratory failed to follow manufacturer's instructions when 424 out of 1,078 patients specimens were processed and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Image Navigator microscope when 1,078 out of 1,078 patients specimens were examined and reported for ANA quantitative tests from June 16, 2017 to March 25, 2019).