Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0689663	01/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Bayamon	Calle Parque Esq Rossi Local 4, Bayamon, 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	BACTERIOLOGY CFR(s): 493.1201 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. This CONDITION is not met as evidenced by: Based on Xpert Chlamydia trachomatis (CT) /Neisseria gonorrhea (NG) Assay (GeneXpert system) testing records, l from December 18, 2017 to January 2, 2020 reviewed, technical consultant (MT # 4) and technical supervisor (MT # 3) interview on January 3, 2020 at 10:21 AM, it was determined that the laboratory failed to meet with the requirement for bacteriology subspecialty (detection of the Xpert CT/NG tests). Refer to D 5449 - The laboratory did not include each day of testing a negative and a positive control material when patient's specimens were tested and reported for the detection of Xpert CT/NG from December 18, 2017 to January 2, 2020.
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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual reviewed and interview with the technical supervisor (TM#3) at 10:10 AM on January 3, 2020, it was determined that

	the laboratory failed to meet the requirement of the General Immunology specialty (ANA tests). Refer to D 5405 (1) Refer to D 5405 (2)
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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records reviewed and interview with the technical supervisor (TM#3) at 10:10 AM on January 3, 2020, it was determined that the laboratory failed to follow manufacturer's instructions for the step by step performance of the ANA screening qualitative tests when 901 out of 913 patient's specimens were processed and reported for ANA tests from January 9, 2017 to January 2, 2020. The findings include: a. The laboratory performed manually the ANA qualitative tests by Immuno Concepts HEp-2000 Colorzyme ANA-Ro method to determine a screening qualitative ANA pattern detection in patients specimens from January 9, 2017 to January 2, 2020. b. The Immuno Concepts HEp-2000 Colorzyme ANA-Ro manufacturer instructed the laboratory for the screening ANA test to dilute patient sample to 1:40 by adding 0.05 ml patient serum to 1.95 ml reconstitute phosphate buffered saline (PBS). c. On January 3, 2020 at 10:10 AM. the ANA qualitative testing records showed that the laboratory did not document the step by step performance of the ANA screening procedures. The laboratory did not document in the testing records the 1:40 dilution when it processed the ANA screening tests in 901 out of 913 patient's specimens from January 9, 2017 to January 2, 2020. The laboratory documented in the testing records the interpretation of patients results performed by the microscopic examination (positive or negative results). d. The technical supervisor (TM#3) confirmed on January 3, 2020 at 10:10 AM, that the laboratory did not document the patient's serum 1:40 dilution of those patient's sample. He stated that the laboratory performed the dilutions but only recorded the interpretation of patients results performed by the microscopic examination. 2. Based on Immuno Concepts HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual reviewed and interview with the technical supervisor (TM#3) at 10:10 AM on January 3, 2020, it was determined that the laboratory failed to follow manufacturer's instructions for the reporting of the ANA screening results when 216 out of 216 were reported with positive results for ANA tests from January 9, 2017 to January 2, 2020. The findings include: a. The laboratory performed manually the ANA qualitative tests by Immuno Concepts HEp-2000 Colorzyme ANA-Ro method to determine a screening qualitative ANA pattern detection in patient's specimens from January 9, 2017 to January 2, 2020. b. The Immuno Concepts HEp-2000 Colorzyme ANA-Ro manufacturer instructed the laboratory for the reporting of results of the screening ANA test that the results should be reported as strongly positive or positive at the 1:40 dilution, and the nuclear pattern should be reported. c. On January 3, 2020 at 10:10 AM. the ANA tests reports records showed that the laboratory reported 216 out of 216 patient's ANA reports as positive 1:40 with the nuclear staining pattern. The laboratory reported those patient's specimens as final result, the 216 ANA tests reports did not indicate

	that the tests is a screening test. d. The procedures manual was not revised since January 23, 2012. The procedures manual did not include instructions for the reporting of the ANA screening test. e. The technical supervisor (TM#3) confirmed during the interview on January 3, 2020 at 10:10 AM, that the laboratory reported those patient's specimens as final result, the 216 out of 216 ANA tests reports were reported positive 1:40 and those did not indicate that the ANA tests is a screening test.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Xpert Chlamydia trachomatis (CT) /Neisseria gonorrhea (NG) Assay testing records, quality control from December 18, 2017 to January 2, 2020 reviewed, technical consultant (MT # 4) and technical supervisor (MT # 3) interview on January 3, 2020 at 10:21 AM, it was determined that the laboratory did not include each day of testing a negative and a positive control material when 2,474 out of 2,474 patient's specimens were tested and reported for detection of Xpert CT/NG from December 18, 2017 to January 2, 2020 by GeneXpert system. The findings include: 1. The laboratory used the Xpert CT/NG Assay (GeneXpert system) for detection of Chlamydia trachomatis (CT) and Neisseria gonorrhea (NG) in patient's samples. 2. On January 2, 2020 at 10:21 AM, the Xpert CT/NG testing records showed that the laboratory did not include each day of testing the negative and positive control materials when 2,474 out of 2,474 patient's specimens were processed from December 18, 2017 to January 2, 2020. 3. The laboratory includes the negative and the positive control materials when it placed in routine use the following lots numbers of Xpert CT /NG reagents kit: Date open lots # exp. Date 12/18/2017 1000066568 7/7/2018 01/08 /2018 1000066568 7/7/2018 02/16/2018 1000075665 11/03/2019 03/23/2018 1000079148 01/19/2019 05/28/2018 1000081930 03/22/2020 06/29/2018 1000099036 12/22/2019 07/11/2018 1000099036 12/22/2019 10/16/2018 1000099023 05/17/2020 01/12/2019 1000098734 05/03/2020 02/14/2019 1000141793 03/14/2020 04/24/2019 1000141793 03/14/2020 08/26/2019 1000162385 05/30/2020 4. The general supervisor (Technical Supervisor - MT # 3) and testing personnel (Technical Consultant - MT # 4) confirmed on January 3, 2020 at 10:21 AM, that the laboratory did not include the negative and the positive control materials each day of testing, instead the laboratory includes a negative and a positive control materials when it placed in routine use every new lot or new shipping of Xpert CT/NG reagents kit. 5. The laboratory tested and reported 2,474 out of 2,474 patient's specimens for the detection of CT/NG tests from December 18, 2017 to January 2, 2020 by the Xpert CT/NG system.
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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual, Xpert CT/NG testing records, Xpert CT/NG quality control from December 18, 2017 to January 2, 2020 reviewed, interview with the technical supervisor (TM#3) and testing personnel (TM # 4) interview on January 3, 2020 at 10:21, it was determined that the laboratory director failed to 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. 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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual, Xpert CT/NG testing records, Xpert CT/NG quality control from December 18, 2017 to January 2, 2020 reviewed, interview with the technical supervisor (TM#3) and testing personnel (TM # 4) interview on January 3, 2020 at 10:21, it was determined that the laboratory director failed to comply with the requirement of the General Immunology specialty (ANA tests) and Bacteriology subspecialty (detection of the Xpert CT/NG tests). Refer to D 5002 Refer to D 5014.
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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual reviewed and interview with the technical supervisor (TM#3) at 10:10 AM on January 3, 2020, it was determined that the technical supervisor failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system (ANA tests). Refer to D 6117.
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 HEp-2000 Colorzyme ANA-Ro manufacturer's instruction, antinuclear antibody (ANA) qualitative testing records (years 2017 to 2020), ANA tests reports records, procedures manual reviewed and interview with the technical supervisor (TM#3) at 10:10 AM on January 3, 2020, it was determined that the technical supervisor director failed to comply with the requirement of the General Immunology specialty (ANA tests). Refer to D 5014.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Xpert Chlamydia trachomatis (CT) /Neisseria gonorrhea (NG) Assay testing records, quality control from December 18, 2017 to January 2, 2020 reviewed, technical consultant (MT # 4) and technical supervisor (MT # 3) interview on January 3, 2020 at 10:21 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D5449 - The laboratory did not include each day of testing a negative and a positive control material when patients were tested and reported for detection of Xpert CT/NG from December 18, 2017 to January 2, 2020.