Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1043613	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Ginara	1253 Calle Juan Baez Urb San Martin, Rio Piedras, 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
D5012	SYPHILIS SEROLOGY CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, 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 Immunostix-rpr manufacturer's instruction, syphilis serology testing record review and technical supervisor interview on February 7, 2018 at 11:05 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory did not follow the Immunostix-rpr manufacturer's instruction when 42 out of 42 patients specimens were tested and reported for syphilis serology tests by the rapid plasma reagin (RPR) method from November 7, 2017 to December 23, 2017. Refer to D 5479.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on QA preanalytic system assessment records review and technical supervisor

	interview on February 7, 2018 at 9:00 AM, it was determined that the laboratory failed to take corrective actions and failed to review the effectiveness of the corrective actions to resolve and prevent recurrence of problems in the preanalytic systems from December 1, 2016 to December 14, 2017. The findings include: 1. The QA preanalytic system assessment records showed that the laboratory did not performed the annual assessment of the preanalytic system in December 2016 due to the laboratory can obtained the evaluation data from the new laboratory information system. 2. The QA preanalytic system assessment records showed no corrective actions nor review the effectiveness of the corrective actions documented to resolve and prevent recurrence of problems in the preanalytic systems from December 1, 2016 to December 14, 2017. The laboratory performed the next evaluation in December 15, 2017. 3. The technical supervisor confirmed on February 7, 2018 at 9:00 AM, that the laboratory did not performed the annual assessment of the preanalytic system in December 2016 due to the laboratory can obtained the evaluation data from the new laboratory information system and the next evaluation was performed in December 15, 2017.
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 Detector/ lex-CRP manufacturer's instructions, C reactive protein (CRP) testing records (2016, 2017) review and interview with the technical supervisor on February 7, 2018 at 10:40 AM, it was determined that the laboratory failed to follow manufacturer's instruction when 17 out of 17 CRP patient's samples were reported for negative qualitative CRP tests by the Detector/ lex-CRP method from January 12, 2017 to December 21, 2017. The findings include: 1. The Detector/ lex-CRP manufacturer's instructed the laboratory to check all negative seras by retesting at a 1: 10 dilution due to a prozone phenomena prior to reported the results. 2. The CRP testing records showed that the laboratory did not follow the manufacturer instructions, the laboratory did not check all CRP negative seras by retesting at 1:10 dilution before it reported as negative results from January 12, 2017 to December 21, 2017. 3. The Technical supervisor confirmed February 7, 2018 at 10:50 AM, that the laboratory did not check all CRP negative seras by retesting at 1:10 dilution before it reported as negative result. 4. The CRP testing records showed that the laboratory did not dilute 17 out of 17 CRP negative patient's specimens prior it reported as negative result from January 12, 2017 to December 21, 2017(one patient specimen reported on January 12, 2017, three patients specimens reported on January 23, 2017, three patients specimens reported on February 3, 2017, three patients specimens reported on March 11, 2017, one patient specimen reported on April 17, 2017, one patient specimen reported on May 22, 2017, one patient specimen reported on May 23, 2017, one patient specimen reported on June 29, 2017, one patient specimen reported on August 24, 2017, one patient specimen reported on November 30, 2017 and one patient specimen reported on December 21, 2017).
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on complete cell count (CBC) quality control records review and interview with the technical supervisor on February 7, 2018 at 10:10 AM, it was determined that the laboratory failed to verify the stated value of the new lot CBC commercially assayed control materials from January 19,2017 to July 5, 2017. The finding include : 1. The CBC quality control records showed that the laboratory did not verify the new lots of CBC control materials (lot 70030711, 70030712 and 70030710) prior to placed in routine on January 19,2017 (those lots of CBC control materials were used in the laboratory until April 12, 2017). 2. The CBC quality control records showed that the laboratory did not verify the new lots of CBC control materials (lot 70870711, 70870712 and 70870710) prior to placed in routine use on April 13, 2017 (those lots of CBC control materials were used in the laboratory until July 5, 2017). 3. The technical supervisor confirmed on February 7, 2018 at 10:20 AM, that the laboratory did not verify those new lots of CBC control materials prior to placed in routine. 4. The technical supervisor stated on February 7, 2018 at 10:20 AM, that the laboratory processed and reported 2,233 out of 2,233 CBC patients specimens from January 19,2017 to July 5, 2017.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Immunostix-rpr manufacturer's instruction, syphilis serology testing record review and technical supervisor interview on February 7, 2018 at 11:05 AM, it was determined that the laboratory failed to follow the Immunostix-rpr manufacturer's instruction when 42 out of 42 patients specimens were tested and reported for syphilis serology tests by the rapid plasma reagin (RPR) method from November 7, 2017 to December 23, 2017. The findings include: 1. The Immunostix-rpr manufacturer's instruction establishes the following: that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. Also, the manufacturer's requires that the laboratory must perform the needle calibration, verify the rotator rpm and monitor the room temperature in the laboratory

	each day of testing. 2. The syphilis serology testing record showed that the laboratory did not include the three levels of control materials nor perform the needle calibration, nor verify the rotator rpm nor monitor the room temperature when 42 out of 42 patients specimens were tested and reported for syphilis serology tests by the rapid plasma reagin (RPR) method from November 7, 2017 to December 23, 2017. 3. The technical supervisor confirmed on February 7, 2018 at 11:15 AM, that the syphilis serology testing record did not include the quality control information in the serology quality control from November 7, 2017 to December 23, 2017 and she stated that the quality control procedures were performed those days but the controls results were not recorded.
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 Immunostix-rpr manufacturer's instruction, Detector/ lex-CRP manufacturer's instructions, syphilis serology testing record, complete cell count (CBC) quality control records, C reactive protein (CRP) testing records (2016, 2017), Quality Assessment (QA) records review and technical supervisor interview on February 7, 2018 at 11:05 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093. 2. The laboratory director did not comply with the quality assessment requirements. Refer to D 6094.
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 Immunostix-rpr manufacturer's instruction, Detector/ lex-CRP manufacturer's instructions, syphilis serology testing record, complete cell count (CBC) quality control records, C reactive protein (CRP) testing records (2016, 2017) review and technical supervisor interview on February 7, 2018 at 11:05 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for syphilis serology, CBC tests and CRP qualitative tests. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of syphilis serology. Refer to D 5012. 2. The laboratory director failed to ensure compliance with the analytic system requirements of CBC tests. Refer to D 5469. 3. The laboratory director failed to ensure compliance with the requirements of the CRP qualitative tests. Refer to D 5479.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 QA preanalytic system assessment records review and technical supervisor interview on February 7, 2018 at 9:00 AM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) pre-analytic system requirements. The finding includes: 1. The laboratory director did not ensure that the laboratory take, document corrective actions nor review the effectiveness of the corrective actions to resolve and prevent recurrence of problems in the preanalytic systems from December 1, 2016 to December 14, 2017. Refer to D 5391.
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 Immunostix-rpr manufacturer's instruction, Detector/ lex-CRP manufacturer's instructions, syphilis serology testing record, complete cell count (CBC) quality control records, C reactive protein (CRP) testing records (2016, 2017) review and technical supervisor interview on February 7, 2018 at 11:05 AM, it was found that the technical supervisor failed to ensure compliance with the analytic system requirements for syphilis serology, CBC tests and CRP qualitative tests. Refer to D 5405. Refer to D 5459. Refer to D 5479.