Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0675423	08/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rosario	Calle C Blq A-24 Jardines De Carolina, Carolina, 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 syphilis serology quality control records review, manufacturer's instructions and laboratory director interview on August 31, 2018 at 10:15 AM, it was determined that the laboratory failed to included meet the requirements for syphilis serology by Rapid Plasma Reagin (RPR) tests. Refer to D5411 and D5451.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records from January 2, 2018 to August 29, 2018, manufacturer's instructions review and laboratory director interview on August 31, 2018 at 10:15 AM, it was determined that the laboratory failed to follow manufacturer's instructions to perform the needle calibration each day of use as required by the ASI Rapid Plasma Reagin (RPR) method. The findings include: 1. The laboratory performed Rapid Plasma Reagin (RPR) by ASI method. 2. The manufacturer's requires that the laboratory must verify the needle calibration (0.5 ml -

	30 1 drop) each day of use. 3. From January 2, 2018 to August 29, 2018, showed that the laboratory did not verify nor document the needle calibration in the RPR (Rapid Plasma Reagin) testing area in those days. 4. The laboratory processed and reported 459 RPR patient's samples tests from January 2, 2018 to August 29, 2018. 5. The laboratory director confirmed on August 31, 2018, that the laboratory did not verify and document the needle calibration from January 2, 2018 to August 29, 2018.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review from January 2, 2018 to August 29, 2018 and laboratory director interview on August 31, 2018 at 10:13 AM, it was determined that the laboratory failed to include at least once a day , a negative control material and a control material with tittered reactivity when patients were tested for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. The findings include: 1. The laboratory performed Rapid Plasma Reagin (RPR) by ASI RPR Reagents set. 2. Review of syphilis serology quality control from January 2, 2018 to August 29, 2018, showed that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when the following patient specimen was processed and report on May 14, 2018 (ID # 2018-321, R 1:128 dils., ID # 2018-323, R 1:128 dils., ID # 2018- 324, R 1:128 dils), May 16, 2018 (ID # 204298, R 1:2 dils.) and July 25, 2018 (ID # 205832, R 1:4 dils.). 3. The laboratory director confirmed on August 31, 2018, that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when patients specimens were tested for syphilis serology quantitative those days.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, syphilis serology quality control records review and laboratory director interview on August 31, 2018 at 10:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: 1. failed to follow the manufacturer's instructions to verify and document the needle calibration.

	Refer to D 5411. 2. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative Rapid Plasma Reagin (RPR) by ASI. Refer to D5451.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on manufacturer's instructions , quality control records review and laboratory director interview on August 31, 2018 at 11:56 AM, it was determined that the laboratory director failed to fulfill her 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 requirements for analytical systems and quality assessment requirements. Refer to D6020 and D6021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, quality control records review and laboratory director interview on August 31, 2018 at 11:56 AM, it was determined that the laboratory director failed to ensure compliance with requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. failed to follow the manufacturer's instruction to verify and document the needle calibration. Refer to D5411. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative Rapid Plasma Reagin (RPR) by ASI. Refer to D5451.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on Quality Assessment (QA) records review and laboratory director interview on August 31, 2018 at 11:58 AM, it was determined that the laboratory director failed to ensure compliance with QUA requirements. The finding includes: 1. The laboratory director did not evaluate the established Quality Assessment Program to monitor and document the following requirement for analytic systems: a. failed to follow the manufacturer's instruction to verify and document the needle calibration. Refer to D 5411. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative Rapid Plasma Regain (RPR) by ASI. Refer to D5451.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 procedures manual, quality control records review and laboratory director interview on August 31, 2018, it was determined tat the testing personnel failed to follow the quality control requirements. The finding includes: 1. The laboratory testing personnel failed to following quality control procedures: a. failed to follow the manufacturer's instruction to verify and document the needle calibration. Refer to D 5411. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative Rapid Plasma Regain (RPR) by ASI. Refer to D5451.