Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2037283	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Laboratorio Analisis Clinico	# 107 Calle Ortegon Caparra Gallery Suite 105, Guaynabo, 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 manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing, Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent records review and technical supervisor # 2 interview on August 30, 2018 at 10:50 AM, it was determined that the laboratory failed to meet the the requirements for syphilis serology (quantitative RPR test) from April 30, 2018 to August 30, 2018. The findings include: 1. The laboratory did not perform the quantitative RPR test in accordance with the manufacturer's instructions of BD Macro-Vue RPR and modified the quantitative RPR test procedures (BD Macro-Vue RPR Cards). Refer to D 5403. 2. The laboratory did not establish the analytical sensitivity (detection limits) of the BD Macro-Vue RPR Cards reagent (modified FDA cleared test) prior to reporting patient RPR quantitative tests. Refer to D 5423. 3. The laboratory failed to test at least once a day a tittered reactivity control material and a negative control material when patients specimens were tested and reported for RPR quantitative tests. Refer to D 5451. .
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 Quality Assessment (QA) records review(year 2018), test reports records review, directs observation of the area where the patients specimens are received and interview with the laboratory staff on August 30, 2018 at 1:00 PM, it was determined that the laboratory failed to evaluate the effectiveness of the corrective actions taken to resolve problems related to the time of specimen collection documented in the Test Order form of the laboratories who refered patients specimens to Quest. The findings include: 1. The laboratory did not evaluate the effectiveness of the corrective actions taken to resolve problems related with the lack of the time of specimen collection documented in the Test Order form of the laboratories who referred patients specimens to Quest, to prevent recurrence. 2. On August 30, 2018 at 1:00 PM, the pre-analytic area QA records (2018) showed that the laboratory took and documented corrective actions when it received the laboratory Tests Order form without the time of specimen collection, but the problems recur. 3. The laboratory staff confirmed on August 30, 2018 at 1:00 PM, that the laboratory took and documented corrective actions when it received this form without the time of specimen collection. He stated that Quest have different type of Test Order form and the manual Order Form was the form with major recurrence for this problem. 4. The tests reports records showed 7 out of 7 patients tests reports with problems related the sample collection time from August 27, 2018 to August 29, 2018: a. One out of 7 patients tests results did not include the time of sample collection: patient ID 1000214768. b. 6 out of 7 patients tests results included the same time for the sample collection date and for the order date: patients ID 1000215930, patient ID 1000215929, patient ID 1000217542, patients ID 1000213805, patient ID 1000215915 and patient ID 1000218923.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	Based on manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing records review and technical supervisor # 2 interview on August 30, 2018 at 10:40 AM, it was determined that the laboratory failed to perform the quantitative RPR test in accordance with the manufacturer's instructions of BD Macro-Vue RPR Cards and modified the quantitative RPR test procedures when 86 out of 86 patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. The findings include: 1. The laboratory did not perform the quantitative RPR test in accordance with the manufacturer's instructions of BD Macro-Vue RPR and modified the quantitative RPR test procedures (BD Macro-Vue RPR Cards) when 86 out of 86 patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. 2. BD Macro-Vue RPR Cards manufacturer instructed the laboratory for the quantitative RPR procedures to report in terms of the highest dilution giving a reactive reaction, including minimal to moderate reaction. If the highest dilution tested 1:16 is reactive, proceed to making an 1:32 and higher dilutions. 3. On August 30, 2018 at 10:40 AM,the SOP for the quantitative RPR tests establish to perform the following dilutions: 1:1, 1:2, 1:4, 1:8 and 1:16. If the highest dilution tested (1:16) is reactive; the following dilution will be prepared 1:32, 1:64, 1: 128, 1:256, and 1:512,respectively. The quantitative test is repeated until an endpoint titer is obtained. The repeat criteria and resulting instruction showed that the highest results to display on report is reactive on 1:16, 384.. 4. The RPR testing records showed that the laboratory performed and reported the following dilutions for 86 out of 86 patients specimens for RPR quantitative tests from April 30, 2018 to August 30, 2018.: 1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128 and 1:256. The laboratory reported the higher dilution of 1:256 without knowing if the patients is reactive at a higher dilution. 5. The technical supervisor # 2 confirmed on August 30, 2018 at 10:40 AM, that the laboratory performed serial dilutions of 1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1: 128 and 1:256 when 86 out of 86 patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. 6. The laboratory displayed on reports the following patients RPR quantitative results from April 30, 2018 to August 30, 2018: Dilutions number of patients performed specimens 1:1 7 1:2 18 1:4 14 1:8 14 1:16 8 1:32 8 1:64 6 1:128 8 1:256 3
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on Policy for Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent, RPR testing records review and technical supervisor # 2 interview on August 30, 2018 at 10:40 AM, it was determined that the laboratory failed to establish the analytical sensitivity (detection

	limits) of the BD Macro-Vue RPR Cards reagent (modified FDA cleared test) prior to reporting patient RPR quantitative tests from April 30, 2018 to August 30, 2018. The findings include: 1. The laboratory modified the quantitative RPR test procedures (BD Macro-Vue RPR Cards) when 86 out of 86 patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. Refer to D 5403. 2. The laboratory Policy for Laboratory Method Validation showed that the laboratory must establish the analytic sensitivity(detection limits) for the performance characteristic of the modified FDA cleared test. 3. The validation records for the BD Macro-Vue RPR Cards reagent showed that the laboratory director accepted the validation of this reagent on April 4, 2018. However, the laboratory did not establish the analytic sensitivity (detection limits) of this method. The laboratory performed the comparison study with 22 patients specimens; 19 out of 22 were non-reactive patients specimens and 3 out of 22 patients specimens were tested for quantitative RPR results (two out of 3 patient with reactive dilutions of 1:2 and one patient with reactive dilution of 1:64). Also, the validation showed that the laboratory tested the higher dilution of the reactive control at 1:4. 4. The laboratory displayed on report the following patients specimens with RPR quantitative results from April 30, 2018 to August 30, 2018: Dilutions number of patients performed specimens 1:1 7 1:2 18 1:4 14 1:8 14 1:16 8 1:32 8 1:64 6 1:128 8 1:256 3
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 BDMacro-Vue RPR Cards testing records review and technical supervisor # 2 interview on August 30, 2018 at 10:40 AM, it was determined that the laboratory failed to test at least once a day a titered reactivity control material and a negative control material when 86 out of 86 patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. The findings include: 1. The laboratory processed quantitative and qualitative RPR patients specimens by the BD Macro-Vue RPR Cards from April 30, 2018 to August 30, 2018. 2. On August 30, 2018 at 10:40 AM,the BDMacro-Vue RPR Cards testing records showed that the laboratory did not test at least once a day a titered reactivity and a negative control material when patients specimens were tested and reported for RPR quantitative tests from April 30, 2018 to August 30, 2018. 3. The technical supervisor # 2 confirmed on August 30, 2018 at 10:50 AM, that the laboratory did not test at least once a day a titered reactivity and a negative control material when patients specimens were tested and reported for RPR quantitative tests. Instead, the laboratory included those control when it performed the RPR qualitative tests. 4. The laboratory processed and reported 86 out of 86 patients specimens for RPR quantitative tests from April 30, 2018 to August 30, 2018: Dilutions number of patients performed reports 1:1 7 1:2 18 1:4 14 1:8 14 1:16 8 1:32 8 1:64 6 1:128 8 1:256 3
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 manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing, Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent records, Quality Assessment (QA) records review (year 2018), test reports records review, directs observation of the area where the patients specimens are received, laboratory staff and technical supervisor # 2 interview on August 30, 2018 at at 1:00 PM, it was as determined that the laboratory director failed to fulfill his responsibilities and duties to comply with the analytic system and QA requirements. Refer to D 6093 and 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 manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing, Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent records review and technical supervisor # 2 interview on August 30, 2018 at 10:50 AM, it was determined that the laboratory director failed to ensure that the analytic requirements for syphilis serology (quantitative RPR test) are established and maintained to assure the quality of laboratory services provided. Refer to D 5012.
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 Quality Assessment (QA) records review(year 2018), test reports records review, directs observation of the area where the patients specimens are received and interview with the laboratory staff on August 30, 2018 at 1:00 PM, it was determined that the laboratory director failed to ensure that the quality assessment programs for the pre-analytic system are maintained. Refer to D 5393. .
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 manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing, Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent records review and technical supervisor # 2 interview on August 30, 2018 at 10:50 AM, it was determined that the laboratory failed to establish and maintain the analytic requirements for syphilis serology (quantitative RPR test). The findings include: 1. The laboratory did not perform the quantitative RPR test in accordance with the manufacturer's instructions of BD Macro-Vue RPR and modified the quantitative RPR test procedures (BD Macro-Vue RPR Cards). Refer to D 5403. 2. The laboratory did not establish the analytical sensitivity (detection limits) of the BD Macro-Vue RPR Cards reagent (modified FDA cleared test) prior to reporting patient RPR quantitative tests. Refer to D 5423. 3. The laboratory failed to test at least once a day a titered reactivity control material and a negative control material when patients specimens were tested and reported for RPR quantitative tests. Refer to D 5451. .
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 manufacturer's instructions of BD Macro-Vue RPR Cards, rapid plasma reagin (RPR) standard operation manual (SOP), RPR Cards, RPR testing, Laboratory Method Validation of modified FDA cleared test, validation records for the BD Macro-Vue RPR Cards reagent records review and technical supervisor # 2 interview on August 30, 2018 at 10:50 AM, it was determined that the testing personnel failed to follow quality control procedures for syphilis serology (quantitative RPR test). The finding includes: 1. The laboratory failed to test at least once a day a titered reactivity control material and a negative control material when patients specimens were tested and reported for RPR quantitative tests. Refer to D 5451. .