Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2006909	09/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics	Mm 9 Iturregui Avenue, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records, syphilis serology quality control review from January 9, 2017 to September 13, 2018, laboratory director and testing personnel interview on September 14, 2018 at 10:23 AM, it was determined that the laboratory failed to enroll in a Department of Health and Human Services (HHS) approved Proficiency Testing Program for a syphilis serology quantitative tests (Rapid Plasma Reagin - RPR). The findings include: 1. The laboratory processed and reported patient specimens for syphilis serology by Rapid Plasma Reagin (AIM RPR) tests from January 9, 2017 to September 13, 2018. 2. The Puerto Rico Proficiency Testing Program (PRPTP) records, showed that the laboratory was enrolled and participate in syphilis serology qualitative tests (RPR) from January 9, 2018 to September 13, 2018, but not enrolled in syphilis serology quantitative. 3. Review of syphilis serology quality control records, showed that the laboratory processed and report the syphilis serology quantitative (RPR) on January 11, 2018 (patient ID # 111211 - R 1:4 dils.) and August 21, 2018 (patient # 123500 - R 1:2 dils.). 4. Review of syphilis serology quality control (RPR) from January 2, 2018 to September 13, 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 January 11, 2018 (patient ID # 111211 - R 1:4 dils.) and August 21, 2018 (patient # 123500 - R 1:2 dils.). 5. The laboratory director confirmed on September 14, 2018, that the laboratory did not enroll in syphilis serology quantitative and not include at least once a day, a negative control material and a control material with tittered reactivity when patient specimens were tested for syphilis serology quantitative (RPR) those days. 6. The laboratory processed and report 408 patient specimens by RPR from January 9, 2017 to September 13, 2018.
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 Puerto Rico Proficiency Testing Program (PRPTP) records, syphilis serology quality control review from January 9, 2017 to September 13, 2018, laboratory director and testing personnel interview on September 14, 2018 at 10:23 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory is enroll in a Department of Health and Human Services (HHS) approved Proficiency Testing Program. The finding includes: 1. The laboratory director did not comply with the requirement for ensure that the laboratory enroll in an HHS approved proficiency testing program for syphilis serology quantitative tests (Rapid Plasma Reagin - RPR) from January 9, 2017 to September 13, 2018. Refer to D6015.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records, syphilis serology quality control review from January 9, 2017 to September 13, 2018, laboratory director and testing personnel interview on September 14, 2018 at 10:23 AM, it was determined that the laboratory director failed to ensure that the laboratory is enroll in a Department of Health and Human Services (HHS) approved Proficiency Testing Program for the following tests: syphilis serology quantitative tests (Rapid Plasma Reagin - RPR). The finding includes: 1. The Puerto Rico Proficiency Testing Program (PRPTP) records, showed that the laboratory was enroll and participate in syphilis serology qualitative tests (RPR) from January 9, 2018 to September 13, 2018, but not enroll in syphilis serology quantitative. 2. Review of syphilis serology quality control records, showed that the laboratory processed and report the syphilis serology quantitative (RPR) on January 11, 2018 (patient ID # 111211 - R 1:4 dils.) and August

	21, 2018 (patient # 123500 - R 1:2 dils.). 3. Review of syphilis serology quality control (RPR) from January 2, 2018 to September 13, 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 January 11, 2018 (patient ID # 111211 - R 1:4 dils.) and August 21, 2018 (patient # 123500 - R 1:2 dils.). 4. The laboratory director confirmed on September 14, 2018, that the laboratory did not enroll in syphilis serology quantitative and not include at least once a day, a negative control material and a control material with tittered reactivity when patient specimens were tested for syphilis serology quantitative (RPR) those days. 5. The laboratory processed and report 408 patient specimens by RPR from January 9, 2017 to September 13, 2018.