Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2037283	09/25/2020
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
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of test records, manufacturers instructions and interview with the laboratory operation manager and quality assessment manager it was determined , that the laboratory failed to ensure compliance with the analytic system requirements for virology tests (SARS-CoV-19). The findings include: 1. The laboratory test results showed inconsistency with initially reported (positive and or negative results) and later rerun tests. D 5413 2. The laboratory did not follow manufacturer's instructions regarding use of laboratory coats. D 5405.
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 review of the Abbott M 2000 rt manufacturer's instructions and interview with the laboratory quality assessment manager and the reference laboratory director of operations, it was determined that the laboratory did not follow the manufacturer's

	instructions regarding the work areas. The findings include: 1. The Abbott M 2000 rt instrument was located at the bacteriology area. 2. Review of the manufacturer's instructions on 9/21/2020 at 9:30 AM., showed that: " The use of two dedicated areas (Sample preparation and Amplification) within the laboratory is recommended when performing the Abbott Real tome SARS-CoV-2 assay. 3. The manufacturer also instructed the laboratory that laboratory coats pipettes , pipettes tips and vortexes used in the sample preparations area must remain in the area and not be moved to the amplification area. 4. During interview the reference laboratory director of operations stated that the testing personnel used the same laboratory coat at the preparation and amplification area. 5. The reference laboratory director of operations also referred that personnel from Abbott company validated their procedures during the instrument installation period of time.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of quality control procedures, PCR COVID-19 test reports and interview with the laboratory reference laboratory director of operations and the quality assessment manager, it was determined that the laboratory did not assure accurate test results for the Real Time SARS-CoV-2 Polymerase Chain Reaction (RT-PCR) test performed by the Abbott M2000rt instrument. The findings include: 1. The laboratory used the Abbott M2000rt instrument to perform Real Time SARS-CoV-2 tests. 2. On September 17, 2020 a complaint was received from the Department of Health Epidemiologist Division. The lead epidemiologist referred that several samples collected at venues of the National Guard (NG) showed initially positives test results and after the rerun of samples, at a different laboratory, they were reported as negatives ones. 3. The investigation began on 9/18/2020 at 9:30 AM and contunue on 9/21/2020 and 9/25/2020. 4. The epidemiologist informed that 40 out of 49 test reports, collected at a N.G. venue on 9/10/2020 and reported on 9/12/2020, showed positive test results. As on 9/20/2020 fifteen (15) of them were repeated (by PCR and serologic tests) at another laboratory showing negative tests reports. 5. On 9/22/2020, 163 samples initially tested on 9/19/2020 were re tested, 23 of them with initially positive tests results showed negative test results and 5 initially negatives showed positive results. The tests were repeated after a decontamination monitoring procedure and with a different extraction kit lot number. The extraction kit lot number used on 9 /19/2020 was the 1001401 and on 9/22/2020 the 1001465. No further explanation was given. The Quest Puerto Rico officials informed that they are requesting an instrument evaluation by the Abbott Company. 6. The extraction kit lot number 1001401 was in use since 8/25/2020. 7. Review of the laboratory' workload since September 11, 2020 showed that the laboratory processed the following: Date Negative Positive Total of Results Results samples 9/11/20 340 152 492 9/12/20 199 259 458 9/13/20 1 1 9/14 /20 109 161 270 9/15/20 317 149 466 9/16/20 300 66 366 9/17/20 207 252 459 9/18 /20 147 309 456 9/19/20 303 79 382 9/20/20 85 7 92 9/21/20 193 55 248 Total 2201

	1489 3690 8. Percentages (%) of positivity were compare between Quest Puerto Rico and the others laboratory's performing RT- PCR, the results showed that since 8/25 /2020,, in 10 out of 23 days , the laboratory showed % of positivity higher than the other laboratories; up to 51.36 % between 9/11/2020 and 9/12/2020.
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:
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of SARS-CoV-2 manufacturer's instructions, performed by the Abbott M 200 rt instrument, and interview with the laboratory operations manager on 9/21/2019 at 10:00 AM, it was determined that the laboratory director did ensure that the testing personnel followed written instructions for laboratory coats changes when performing RT-PCR tests by the Abbott M 200 rt instrument. The finding includes: 1. The testing personnel used that same laboratory coat at the samples preparation and amplification areas. Refer to D5405
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of tests reports and interview with the laboratory operations manager and the quality assessment manager, it was determined that the laboratory did not ensure to maintain acceptable levels of analytical performance when the laboratory SARS-CoV-2 tests results showed % of positivity over the mean of the previously observed. The findings include: 1. Review of test reports showed higher number of positive tests results , at random, since 9/11/2020, however no evaluation of the possible reason was performed . Review D 5413.