Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2037283	08/11/2022
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
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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from January 2, 2022 to August 11, 2022 and laboratory testing personnel interview on August 11, 2022, it was determined that the laboratory failed to follow the manufacturer's instruction when 59 out of 59 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from July 14, 2022 to July 22, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On August 11,

	2022 at 9:38 AM, the Mycoplasma testing records showed that the laboratory tested the patient's specimens over the room temperature establishes (26C) on July 14, 2022 (nine (9) patient's), July 15, 2022 (ten (10) patient's), July 18, 2022 (13 patient's), July 19, 2022 (14 patient's), July 20, 2022 (eight (8) patient's), July 21, 2022 (three (3) patient's) and July 22, 2022 (two (2) patient's). 3. The laboratory testing personnel confirmed on August 11, 2022 at 12:44 PM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 59 out of 59 patients specimens for mycoplasma test by Immuno Card Meridian method from July 14, 2022 to July 22, 2022.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on laboratory procedures manual and bacteriology gram stain quality control records review from June 2022 to August 11, 2022 and laboratory testing personnel interview on August 11, 2022, it was determined that the laboratory was failed to check the Gram stain reactivity with control organism each week of use. The findings include: 1. The laboratory procedures manual established that the laboratory check the Gram stain reactivity with control organism each week of use. 2. On August 11, 2022 at 11:55 AM, showed that the laboratory did not perform and document the check of the Gram stain reactivity each week of use from June 2, 2022 to August 11, 2022. 3. The laboratory testing personnel confirmed on August 11, 2022 at 12:45 PM, that the laboratory failed to follow the procedures to check the Gram stain each week of use from June 2, 2022 to August 11, 2022.
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, general immunology and bacteriology (Gram stain reactivity) quality control records review from January 2, 2022 to August 11, 2022 and laboratory testing personnel interview on August 11, 2022, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5403 (to follow the manufacturer's instruction when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method). Refer to D5503 (to check the Gram stain reactivity with control organism each week of use).
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, general immunology and bacteriology (Gram stain weekly quality control) records review from January 2, 2022 to August 2022 and laboratory testing personnel interview on August 11, 2022, it was determined that testing personnel failed follow quality control requirements for general immunology and bacteriology (Gram stain weekly quality control). Refer to D5403 (the laboratory failed to follow the manufacturer's instructions when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method). Refer to D5503 (laboratory was failed to check the Gram stain reactivity with control organism each week of use).