Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0685119	01/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Laboratorio Analisis Clinico	Carr # 2 Km 11 Hm 8 Edificio Federal, Bayamon, 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 hematology quality control SOP, complete blood cell (CBC) Levy Jenny charts records (year 2018 and 2019) reviewed, interview with the general supervisor and laboratory director at 12:05 PM on January 2, 2020, it was determined that the laboratory failed to follow written procedures to evaluate the hematology quality control when 2,850 out of 2,850 patient's specimens were processed and reported for CBC tests from January 2, 2019 to July 31, 2019 by the Act 5 diff system. The findings include: 1. The laboratory processed and reported the CBC tests by the Act 5

	diff system. 2. The hematology quality control SOP requires to take daily, weekly, or monthly actions to managing an effective Quality Control Program. 3. At 12:05 PM on January 2, 2020, from January 2, 2019 to July 31, 2019 the CBC's Levy Jenny charts records showed the following discrepancies and the laboratory did not take nor document remedial actions: a. The laboratory used the CBC control materials lots 360119, 370119 and 380119 (with expiration date of March 5, 2019) in January 2019 and February 2019. However, the Levy Jenny charts of those months showed that those charts were modified and printed on April 22, 2019 and the expiration date of those CBC's control materials was modified to April 22, 2019. b. The laboratory used the CBC control materials lots 360319, 370319 and 380319 (with expiration date of May 5, 2019) in March 2019. However, the Levy Jenny charts of this month showed that those charts were modified and printed on June 24, 2019 and the expiration date of those CBC's control materials was modified to June 24, 2019. c.The laboratory used the CBC control materials lots 360319, 370319 and 380319 (with expiration date of May 5, 2019) in April 2019. However, the Levy Jenny charts of this month showed that those charts were modified and printed on July 15, 2019 and the expiration date of those CBC's control materials was modified to July 15, 2019. d. The laboratory used the CBC control materials lots 360519, 370519 and 380519 (with expiration date of July 5, 2019) in May 2019. However, the Levy Jenny charts of this month showed that those charts were modified and printed on July 15, 2019 and the expiration date of those CBC's control materials was modified to July 15, 2019. e. The laboratory used the CBC control materials lots 360519, 370519 and 380519 (with expiration date of July 5, 2019) from June 1, 2019 to July 3, 2019. However, the Levy Jenny charts of this month showed that those charts were modified and printed on July 22, 2019 and the expiration date of those CBC's control materials was modified to July 22, 2019. f. The laboratory used the CBC control materials lots 360719, 370719 and 380719 (with expiration date of September 5, 2019) from July 6, 2019 to July 31, 2019. However, the Levy Jenny charts of this month showed that the charts for lots 370719 and 380719 were modified and printed on September 10, 2019 and the expiration date of those CBC's control materials was modified to September 10, 2019. 4. The general supervisor and the laboratory director stated at 12:05 PM on January 2, 2020 that they had not aware for those Levy Jenny charts discrepancies. 5. The laboratory processed and reported 2,850 out of 2,850 patient's specimens for CBC tests from January 2, 2019 to July 31, 2019 by the Act 5 diff system.
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 hematology quality control SOP, CBC's Levy Jenny charts records (year 2018 and 2019) reviewed, interview with the general supervisor and laboratory director at 12:05 PM on January 2, 2020, it was determined that the laboratory director failed to comply with the analytic system requirements for the CBC tests. Refer to D 5403.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463

	The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology quality control SOP, CBC's Levy Jenny charts records (year 2018 and 2019) reviewed, interview with the general supervisor and laboratory director at 12:05 PM on January 2, 2020, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting 2,850 out of 2,850 patient's specimens for CBC tests from January 2, 2019 to July 31, 2019 by the Act 5 diff system. Refer to D 5403.
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 hematology quality control SOP, CBC's Levy Jenny charts records (year 2018 and 2019) reviewed, interview with the general supervisor and laboratory director at 12:05 PM on January 2, 2020, it was determined that the testing personnel failed to follow quality control procedures for the CBC tests when 2,850 out of 2,850 patient's specimens were processed and reported for CBC tests from January 2, 2019 to July 31, 2019 by the Act 5 diff system. Refer to D 5403.