Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667748	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostic Laboratorio De Analisis Clinico	Urb Villa Blanca Pr-1, Km 34 Hm 9 Bo Bairoa, Caguas, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of the levy Jennings charts records (year 2018) for the complete cell count (CBC) controls values, annual test volume records (year 2018) review and general supervisor interview on September 17, 2019 at 10:10 AM, it was determined that the laboratory failed to retained the levy Jennings charts of the CBC controls values during the year 2018. The findings include: 1. The laboratory processed the CBC patients specimens by the Coulter Act 5 diff system. 2. On September 17, 2019 at 10:10 AM, the laboratory did not have available the levy Jennings charts records for the CBC controls values processed during the year 2018. 3. The general supervisor confirmed on September 17, 2019, that the laboratory did not have available the levy Jennings charts records for the CBC controls values processed during the year 2018 by the Coulter Act 5 diff system. She stated that those charts were misplaced. 4. The annual test volume records showed that the laboratory reported 13,185 tests in the Hematology specialty during the year 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on written procedures, annual test volume records review, lack of preventive maintenance records (year 2018) of the Clinitek advantus system and interview with the general supervisor on September 17, 2019 at 12:05 PM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the Clinitek advantus system during the year 2018. The findings include: 1. The The laboratory processed the patients specimens for the urinalysis by the CBC tests by the Clinitek advantus system. 2. The laboratory establishes written procedures to perform the preventive maintenance of the Clinitek advantus system. 3. On September 17, 2019 at 12:05 PM, the laboratory did not have available the preventive maintenance records of the Clinitek advantus system that were performed during the year 2018. 4. The general supervisor confirmed on September 17, 2019 at 10:10 AM, that the laboratory did not have available the Clinitek Advantus preventive maintenance records (year 2018). She stated that the records was misplaced. 5. The annual test volume records showed that the laboratory reported 4,174 tests in the Urinalysis sub-specialty during the year 2018.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of Coulter Act 5 diff calibration records (year 2018), annual test volume records, calibration written procedures review and general supervisor interview on September 17, 2019 at 10:10 AM, it was determined that the laboratory failed to perform every six months the calibration procedures for the complete cell count (CBC) tests performed by the Coulter Act 5 diff system during the year 2018. The findings include: 1. The laboratory processed the patients specimens for the CBC tests by the Coulter Act 5 diff system. 2. The laboratory establishes written procedures to perform every six months the calibration of the Act 5 diff system. 3. On September 17, 2019 at 10:10 AM, the laboratory did not have available the calibration records of the Act 5 diff system that were performed during the year 2018. 4. The general supervisor confirmed on September 17, 2019 at 10:10 AM, that the laboratory did not have available the calibration records of the Coulter Act 5 diff system processed during the year 2018. She stated that those records were misplaced but also stated that the calibration of the Act 5 diff system were performed every 6 months. 5. The annual test volume records showed that the laboratory reported 13,185 tests in the Hematology specialty during the year 2018.
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 lack of the levy Jennings charts records (year 2018) for the CBC controls values, lack of preventive maintenance records (year 2018) of the Clinitek advantus system, lack of Coulter Act 5 diff calibration records (year 2018), annual test volume records, written procedures, annual test volume records (year 2018) review and interview with the general supervisor on September 17, 2019 at 12:05 PM, it was determined that the laboratory director failed to ensure compliance with the analytic requirements of the CBC and urinalysis tests. Refer to D 3031 (The laboratory failed to retained the levy Jennings charts of the CBC controls values during the year 2018). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Clinitek advantus system during the year 2018). Refer to D 5437 (The laboratory failed to perform every six months the calibration procedures for the CBC tests performed by the Coulter Act 5 diff system during the year 2018).
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 lack of the levy Jennings charts records (year 2018) for the CBC controls values, lack of preventive maintenance records (year 2018) of the Clinitek advantus system, lack of Coulter Act 5 diff calibration records (year 2018), annual test volume records, written procedures, annual test volume records (year 2018) review and interview with the general supervisor on September 17, 2019 at 12:05 PM, it was determined that the general superviosr failed to perform day-to-day supervision for the testing personnel under her responsibility. Refer to D 3031 (The laboratory failed to retained the levy Jennings charts of the CBC controls values during the year 2018). Refer to D 5429 (The laboratory failed to follow written instructions for the preventive maintenance of the Clinitek advantus system during the year 2018). Refer to D 5437 (The laboratory failed to perform every six months the calibration procedures for the CBC tests performed by the Coulter Act 5 diff system during the year 2018).