Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0093126	01/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics, Llc	3 Sterling Dr, Wallingford, CT	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform and document calibration verification of coagulation tests at the required frequency. Findings include: 1. Record review of calibration records for coagulation tests on 1/14 /19 revealed the following: a. Calibration documents were not available for Fibrinogen test for the period of 2/17/16 through 6/29/18 for the CA-7000 coagulation analyzer with serial number (SN#) A1442. b. Calibration documents were not

	available for Fibrinogen test for the CA-7000 coagulation analyzer with SN# A1719 in 2017. c. Calibration documents were not available for D-Dimer test for the period of 3/10/17 through 7/25/18 for the CA-7000 coagulation analyzer with SN# A1442. d. Calibration documents were not available for D-Dimer test for the CA-7000 coagulation analyzer with SN# A1719 in 2017. 2. Record review of the laboratory's calibration procedure for coagulation tests on 1/14/19 revealed calibration is required when reagents lot numbers are changed and at least every six months. 3. Staff interview with the technical consultant #1 (TC#1) on 1/14/19 at 11:30 AM confirmed the six months calibration documents were not available for the above indicated periods. TC#1 also stated the CA-7000 analyzer with SN# A1719 was moved back to the laboratory in May 2017. 4. The laboratory performs 130 Fibrinogen and 677 D-Dimer tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the reference ranges reported on the final patient test report did not correlate with the reference ranges in the procedure manual in the specialty of hematology. Findings include: 1. Record review on 1/14/19 of the 'Laboratory Hematology Procedure Manual' compared to final patient test reports revealed: a. The reference range on patient reports did not correlate with the reference range in the procedure manual for Anti-Xa. b. The reference range on the patient report (0.2-2.0 IU/mL) was actually the analytical measurement range (AMR) listed in the procedure. 2. Staff interview with the technical supervisor on 1/14/19 at 11:00 AM confirmed that the reference range listed on the patient report was actually the AMR listed in the procedure manual.