Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099575	12/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Llc	555 Lordship Blvd, Stratford, 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 the calibration verification to include the low, mid and the highest value of the reportable range for D-Dimer in the specialty of Hematology. Findings include: 1. Record review on 12/22/2022 of the laboratory's Method validation D-Dimer on CS-2500 verified the On-Board dilution check, Analytical Measurement Range (AMR): 0.19 to 4.40 mcg /mL FEU and Clinical Reference Range 0.19 to 35.00 mcg/mL FEU. 2. Record

	review on 12/22/2022 of the "Normal Calibration Curve" print out performed on 12/19 /2022 with DDi Reag: 569319, Calibrator/Lot No. 569419 reveals the six-point calibration with the DDI values as follows: 0.15,0.31,0.62,1.25,2.49 and 4.99. 3. Record review on 12/22/2022 of the D-Dimer-CS procedure manual revealed the following: a. Section 10.4: Analytical Measurement Range (AMR): CS series: 0.19-~4.40 mcg/mL FEU (calibrator dependent). With 1:10 dilution, AMR is extended to ~35 mcg/mL FEU (calibrator dependent). b. Section 10.6: Repeat Criteria and Resulting: If the result is "35 with > flag", Repeat. If repeat confirms, report as ">35 mcg/mL FEU". 4. Record review on 12/22/2022 of calibration verification records revealed the following: a. Six-point calibration verification is performed for each new reagent lot. b. The calibration verification material failed to include at least one value near the upper limit of the AMR with 1:10 dilution extended to 35.0 mcg/mL FEU as stated in 3a above. 5. Staff interview on 12/22/2022 at 12:00 PM with the Hematology Technical Supervisor confirmed the above findings. 6. The laboratory performs approximately 1363 tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review on 12/22/2022 of 2 final Complete Blood Count (CBC) test reports revealed the laboratory failed to ensure the normal ranges matched the laboratory established age specific ranges in the specialty of Hematology. Findings include: 1. Record review on 12/22/2022 of the laboratory's Procedure Manual (PM) revealed the laboratory established age specific normal ranges for CBC as follows: 12y, 18y, 133y and No Age. 2. Record review on 12/22/2022 of 2 CBC patient test reports Complete Blood Count (CBC) revealed the following: a. Reference Range attached for Patient A, Sex: Female, age 70 = the laboratory established reference range for age 133 year for the following analytes: Red Blood Cell (RBC), Hemoglobin (HGB), Hematocrit (HCT) and Mean Cell Volume (MCV). b. Reference Range attached for Patient B, Sex: Male, age 100 years = the laboratory established reference range for age 133 years for the following analytes: RBC, HGB, HCT, and MCV. 3. Record review on 12/22/2022 of the Laboratory CBC procedure revealed the procedure failed to establish the process to select which reference range is appropriate for patients that fall outside the laboratory established age specific reference range. 4. Staff interview on 12/22/2022 at 11:30 AM with the Hematology Technical Supervisor confirmed the above findings. 5. The laboratory performs approximately 19357 of RBC, 17317 of HGB, 17256 of HCT, 16727 of MCV tests annually.