Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1034604	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Quest Diagnostics Massachusetts Llc	**Street Address, City, State** 366 Shrewsbury St, Worcester, MA	

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
D0000	A CLIA recertification survey was conducted for the Quest Diagnostics Massachusetts, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain documentation to verify the accuracy of any test or procedure it performs that is not included in subpart I of this part at least semiannually as evidenced by the following: a) The laboratory performs urine total protein and urine creatinine which is not covered by proficiency testing. The laboratory performs internal proficiency testing by having the results sent to another Quest laboratory for comparison. b) A review of calendar years 2017 and 2018 internal proficiency testing results revealed that documentation was not available to verify that cross comparisons were performed during calendar year 2017. The only documentation available was for 6/4/18. c) The technical consultant confirmed in an interview on 9/19/18 at 1:45 PM that cross comparisons had been performed for the above analytes but the documentation could not be located.
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 interview, the laboratory failed to maintain documentation to verify that calibration verifications were performed, as appropriate, as evidenced by the following: a) A review of quality control records for calendar years 2017 and 2018 was performed. The review revealed that documentation of calibration verifications of at least 3 points performed once every six months were not available for one (1) of four (4) chemistry analytes requiring calibration verification on the Siemens Centaur CP chemistry analyzer. Six month calibration verification documentation for serum human chorionic gonadotropin (hCG) was not available for calendar year 2018. The last documented calibration verifications for hCG was performed on 10/2/17. b) The technical consultant interviewed on 9/21/18 at 2:15 PM confirmed that calibration verifications of at least 3 points had been performed at least once every six months for hCG but the documentation could not be located. .