

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0650197	<b>(X3) Date Survey Completed</b>  02/23/2018
<b>Name of Provider or Supplier</b>  Quest Diagnostics Massachusetts Llc	<b>Street Address, City, State</b>  909 Sumner Street, Stoughton, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verification as appropriate as evidenced by the following: a) A review of quality</p>

control records for calendar years 2016 and 2017 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for nineteen (19) out of twenty (20) chemistry analytes on the Beckman AU 480 and one (1) out of four (4) analytes on the Siemens Centaur CP analyzer. The last documented calibration verifications were performed on 9/24/16 on the Beckman AU 480 analyzer and 9/25/16 on the Siemens Centaur CP analyzer. b) The technical consultants interviewed on 2/23/17 at 2:00 PM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for twenty (20) out of twenty four (24) chemistry analytes. c) The laboratory performs a total of 265,500 chemistry tests annually.