Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1034483	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Massachusetts Llc	101 Cedar Street, Milford, 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. .
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 perform calibration verification as appropriate as evidenced by the following: a) A review of quality

	control records for calendar years 2019 and 2020 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for eleven (11) of eleven (11) quantitative chemistry analytes performed (glucose, urea nitrogen, calcium, sodium, potassium, chloride, CO2, total cholesterol, HDL cholesterol, and triglyceride) on the Horiba Pentra C400 chemistry analyzer. Calibration verifications were not performed at least once every six months for the above tests during calendar year 2019. They were only performed once on 9/12/19. b) The technical consultant interviewed on 3/10/21 at 9:50 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for the tests listed above. .