

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D2059744	<b>(X3) Date Survey Completed</b> 08/11/2021
<b>Name of Provider or Supplier</b> Quest Diagnostics Massachusetts Llc	<b>Street Address, City, State</b> 5 Neponset Street, Suite 1581, Worcester, 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>D2004</b>	<p>ENROLLMENT CFR(s): 493.801(a)(3)</p> <p>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review for calendar years 2019, 2020 and 2021 the laboratory failed to participate in one proficiency testing program for one year before designating another program and notifying CMS of the change in designation as evidenced by the following: a) A review of 2019 and 2020 American Proficiency Institute (API) proficiency testing for routine chemistry revealed that the laboratory was enrolled for calendar years 2019 and 2020 for routine chemistry testing in API. A review of CMS report a 0155D - Individual Laboratory Profile (proficiency testing) revealed that the laboratory switched to the College of American Pathologists (CAP) for the third testing event of calendar year 2020 for Routine Chemistry. b) The technical consultant confirmed in an interview on 8/11/21 at 8:40 AM that the laboratory had switched over to CAP for the third testing event of 2020. .</p>
<b>D2005</b>	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service</p>

Act.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to authorize the proficiency testing program to release to HHS all data required to determine the laboratory's compliance with this subpart as evidenced by the following: a) A review of proficiency testing documents for calendar years 2019, 2020 and 2021 on 8/11/21 at 8:45 a.m. revealed that the CLIA number was not listed on the College of American Pathologists (CAP) proficiency testing reports. Review of the CMS CLIA application and summary report revealed no proficiency testing results for the specialty areas of Routine Chemistry (beginning the third testing event of 2020), Endocrinology, and Hematology. b) The technical supervisor confirmed with a CAP representative by phone on 8/11/21 at 9:59 a.m. in the presence of the surveyor that the proficiency testing results were not being reported to HHS. .

**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, 2020 and 2021 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, CO<sub>2</sub>, total cholesterol, HDL cholesterol, and triglycerides) 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 2020. b) The technical consultant interviewed on 8/11/21 at 9:34 a.m. confirmed that the laboratory had not been performing routine

chemistry testing for the first part of 2020 but, in June, the laboratory resumed testing. She further stated that calibration verifications should have been performed upon resumption of testing but were not performed until 3/31/21. .