

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D1034481	(X3) Date Survey Completed 02/10/2021
Name of Provider or Supplier Quest Diagnostics Massachusetts Llc	Street Address, City, State 4 Brotherton Way, Auburn, 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 laboratory Quest Diagnostics Massachusetts, LLC pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2004	<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 and 2020 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 2/10/21 at 8:40 AM that the laboratory had switched over to CAP for the third testing event of 2020.</p>