

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D1034483 | (X3) Date Survey Completed 04/03/2020 |
| Name of Provider or Supplier Quest Diagnostics Massachusetts Llc | Street Address, City, State 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 paper desk review of proficiency testing 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. Based on evidence of unsuccessful proficiency testing performance for the Chloride analyte, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. . |
| D2016 | <p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing review for calendar year 2019 (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in</p> |

the American Proficiency Institute (API) proficiency testing program for the Chloride analyte. Refer to D2096. .

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on an off site desk review of the laboratory's 2019 and 2020 American Proficiency Institute's (API) proficiency testing (PT) records and an email interview with the laboratory general supervisor the laboratory failed to achieve satisfactory performance for the Chloride analyte for two out of three testing events resulting in unsuccessful performance for the analyte as evidenced by the following: 1. Desk review of the laboratory's 2019 and 2020 API PT records revealed the laboratory achieved a score for Chloride scores of less than eighty percent for the following Routine Chemistry testing events: 2019 second testing event - Chloride score of twenty (20) percent; and, 2020 first testing event - Chloride score of sixty (60) percent. 2. In an email received on April 3, 2020 the laboratory general supervisor confirmed the above PT scores were correct.