

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D0365956 | (X3) Date Survey Completed 04/02/2020 |
| Name of Provider or Supplier Steven D Trombly Md | Street Address, City, State 5195 15 Mile Rd, Sterling Heights, MI | |
| 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 |
|---------------------------|---|
| 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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing reports, the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of Endocrinology. Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 2 (2nd 2019 and 1st 2020) of 3 testing events. Refer to D2107 and D2108</p> |
| D2107 | <p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> |

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 review of the CMS database and review of the American Proficiency Institute (API) final proficiency testing (PT) reports, the laboratory failed to achieve satisfactory performance for the Endocrinology analyte Free Thyroxine for 2 (2nd 2019 and 1st 2020) of 3 consecutive testing events, which is unsuccessful performance. Findings include: Free Thyroxine PT Event Score 2nd event 2019 0% 1st event 2020 0%

D2108

ENDOCRINOLOGY
CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 review of the CMS data base and review of the American Proficiency Institute (API) final proficiency testing reports, the laboratory failed to achieve a satisfactory overall performance for Endocrinology which is unsatisfactory performance for the speciality of Endocrinology. Findings include: Unsatisfactory performance for 2 (2nd 2019 and 1 2020) of 3 testing events for the speciality of Endocrinology constitutes unsuccessful performance. Endocrinology PT event Score 2nd event 2019 66% 1st event 2020 66%