

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0365545	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Family Practice Care Pllc	Street Address, City, State 28351 Schoenherr Road, Warren, 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 Association of Bioanalysts (AAB) final graded proficiency testing reports, the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of endocrinology and the analytes Triiodothyronine (TT3), Calcium, total, and Cholesterol, High Density Lipoprotein. Refer to D2107 and D2108.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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:

. American Association of Bioanalysts (AAB), the laboratory failed to achieve successful performance for the analytes, Calcium (CA), total and Cholesterol, High Density Lipoprotein (Chol HDL) in two out of three testing events. Findings include: CA, total Score 1st event 2019 20% 2nd event 2018 0% Chol HDL Score 1st event 2019 60% 2nd event 2018 0%

D2107

ENDOCRINOLOGY

CFR(s): 493.843(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 proficiency testing (PT) desk review and the laboratory's graded PT results from American Association of Bioanalysts (AAB), the laboratory failed to achieve successful performance for the analyte, Triiodothyronine (TT3) in two out of three testing events. Findings include: TT3 Score 1st event 2019 20% 2nd event 2018 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 proficiency testing (PT) desk review and the laboratory's graded PT results from American Association of Bioanalysts (AAB), the laboratory failed to achieve an overall successful performance for the specialty of Endocrinology, in two out of three testing events. Findings include: Endocrinology Score 1st event 2019 73% 2nd event 2018 0%