

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0371470	(X3) Date Survey Completed 09/14/2021
Name of Provider or Supplier Sterling Physicians	Street Address, City, State 36040 Dequindre 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 record review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS-approved proficiency testing program for the General Immunology specialty, the anti-nuclear antibody (ANA), and the chemistry analyte calcium, total. Findings include: Review of the CMS database and the AAB proficiency testing reports revealed the laboratory failed to achieve satisfactory performance for the General Immunology specialty, ANA, and the chemistry analyte calcium, total. Refer to D2076, D2077, and D2089.</p>

<p>D2076</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to attain an overall score of at least 80% for 2 (1st and 2nd) of 2 consecutive testing events in 2021 for the specialty of immunology which is unsatisfactory performance for the testing events. Findings include: General Immunology Score PT Event 1st event 2021 0% 2nd event 2021 0%</p>
<p>D2077</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to participate in 2 (1st and 2nd) of 2 events in 2021 for the general immunology specialty and anti-nuclear antibody (ANA) analyte which is unsatisfactory performance for the testing events. Findings include: General Immunology Score PT Event 1st event 2021 0% 2nd event 2021 0% ANA Score PT Event 1st event 2021 0% 2nd event 2021 0%</p>
<p>D2089</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: . Based on review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing reports, the laboratory failed to participate in 2 (1st and</p>

2nd) of 2 events in 2021 for the chemistry analyte: calcium, total, which is unsatisfactory performance for the testing events. Findings include: Calcium, total
Score PT Event 1st event 2021 0% 2nd event 2021 0%