

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1018843	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Sanford Luverne Medical Center	Street Address, City, State 1600 N Kniss Ave, Luverne, MN	
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 proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to successfully participate in pO2 PT under the specialty of General Chemistry in 2023. Finding are as follows: 1. The CMS CASPER Report 0155D and the API 2023 Chemistry - Core 2nd Event Comparative Evaluation and the 2023 API 2023 Chemistry - Core 3rd Event Performance Summary and Comparative Evaluation were reviewed on November 9, 2023. The reports indicated the laboratory failed to achieve satisfactory performance for pO2 in two consecutive testing events in 2023 resulting in unsuccessful performance. See D2096. .</p>

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 a review of proficiency testing (PT) reports from the Center for Medicare and Medicaid Services (CMS) and the American Proficiency Institute (API), the laboratory failed to achieve satisfactory PT performance for pO₂ testing in two consecutive PT events in 2023, constituting unsuccessful performance. Findings include: 1. The CMS CASPER Report 0155D, reviewed on November 9, 2023, indicated the laboratory failed to obtain a successful score of at least 80 percent in two consecutive testing events in 2023 for pO₂. 2. The API 2023 Chemistry-Core - 3rd Event Performance Summary confirmed the laboratory failed to obtain a pO₂ PT score of at least 80 percent in two consecutive testing events in 2023. -Score of 60% during the 2nd event of 2023 -Score of 60% during the 3rd event of 2023 .