

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0398507	(X3) Date Survey Completed 08/13/2018
Name of Provider or Supplier Essentia Health Sandstone	Street Address, City, State 705 Lundorff Dr, Sandstone, 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 a review of proficiency testing reports from the American Proficiency Institute, the laboratory failed to successfully participate in proficiency testing for pO2 testing under the specialty of Chemistry. Findings are as follows: D2087 - the laboratory failed to obtain a PT score for pO2 testing of at least 80 percent in two testing events D2096 - the laboratory failed to achieve satisfactory performance for pO2 testing in two out of three consecutive testing events</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

. Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score for pO₂ testing of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of pO₂ testing was obtained in the following events. - 2017 3rd event: 40% - 2018 2nd event: 20%

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 American Proficiency Institute (API) provider, the laboratory failed to achieve successful performance for pO₂ testing in two out of three consecutive PT events. Findings are as follows: The laboratory failed pO₂ testing in two out of three consecutive PT events. Two out of three consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from API listed the following unsatisfactory pO₂ scores. - 2017 3rd event: 40% - 2018 2nd event: 20%