Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0398507	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Essentia Health Sandstone	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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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 Blood Cell Identification testing under the specialty of Hematology. Findings are as follows: D2121 - the laboratory failed to obtain a PT score for Blood Cell Identification of at least 80 percent D2127 - the laboratory failed to participate in the 2nd Hematology/Coagulation proficiency testing event in 2017 D2130 - the laboratory failed to achieve successful performance for Blood Cell Identification testing in two consecutive PT events.

D2121	HEMATOLOGY CFR(s): 493.851(a) 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 review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score for Blood Cell Identification of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of Blood Cell Identification was obtained in the following API events. -2017 2nd event 0% -2017 3rd event 60%
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 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 participate in the 2nd Hematology/Coagulation testing event in 2017 which resulted in a score of 0 for all analytes. Findings are as follows: 1. Review of PT results from API revealed that the laboratory failed to participate in the 2nd Hematology/Coagulation testing event of 2017.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to achieve successful performance for Blood Cell Identification testing in two consecutive PT events. Findings are as follows: The laboratory received unsatisfactory scores for Blood Cell Identification testing in two consecutive PT events. Two consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from API listed the following unsatisfactory Blood Cell Identification scores. -2017 2nd event 0% -2017 3rd event 60%