Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0398507	(X3) Date Survey Completed 10/17/2023
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
D0000	The Essentia Health Sandstone laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the Proficiency Testing desk review performed on October 17, 2023. The following condition-level deficiency was cited: 493.803 Successful participation in proficiency testing The following standard-level deficiency was cited: 493.863 Compatibility testing .
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 review of proficiency testing (PT) scores from the American Proficiency Institute (API), the laboratory failed to successfully participate in Compatibility

	Testing PT under the specialty of Immunohematology in 2023. Findings are as follows: 1. The laboratory failed to participate in the 1st Immunohematology testing event in 2023 which resulted in a score of 0% for all analytes. See D2178 2. The laboratory failed to achieve satisfactory performance for Compatibility Testing in two out of three consecutive testing events in 2023, constituting unsuccessful participation for the analyte. D2181 .
D2178	COMPATIBILITY TESTING CFR(s): 493.863(c) 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 1st Immunohematology testing event in 2023 which resulted in a score of 0% for all analytes. Findings are as follows: 1. The API Performance Summary and Comparative Evaluation PT report from the 2023 1st Immunohematology testing event was reviewed on October 17, 2023. 2. The report indicated the laboratory received a 0% score for failure to participate in PT for all Immunohematology analytes, including Compatibility Testing. .
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory 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) scores from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for Compatibility Testing in two out of three consecutive testing events in 2023, constituting unsuccessful participation for the analyte. Findings are as follows: 1. API Performance Summary and Comparative Evaluation PT reports from the 2023 Immunohematology 1st Event and the 2023 Immunohematology 2nd Event were reviewed on October 17, 2023. 2. The reports indicated the laboratory had unsatisfactory performance for Compatibility Testing in two out of three consecutive events, leading to unsuccessful participation. Unsatisfactory PT performance for Compatibility Testing was obtained in the following events: Event Score -2023 1st event 0% -2023 2nd event 80% .