Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0398507	10/30/2020
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee, and/or Testing Personnel, failed to attest to the integration of proficiency testing samples into the routine patient workload on one occasion in 2018, three occasions in 2019, and one occasion in 2020. Findings are as follows: 1. The laboratory performed Chemistry, Microbiology, Immunohematology, and Hematology testing as confirmed by the Technical Supervisor 3 (TS3) during a tour of the laboratory on 10/29/20 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) and College of American Pathologists (CAP) PT providers. 3. The Laboratory Director and Testing Personnel were required to sign the attestation statements as established in the Proficiency Testing policy located in the Laboratory Policies & Procedures manual. 4. The Laboratory Director (LD) or designee, or Testing Personnel (TP), failed to attest to the integration of PT samples into the routine patient workload for 5 of 33 API PT events reviewed in the August 2018 through October 2020 timeframe. See below. Event / Missing attestation documentation 2018-3 Chemistry Core No TP signature 2019-2 Microbiology No LD signature 2019-3 Microbiology No LD signature 2019-3 Immunohematology No LD signature 2020-2 Hematology / Coagulation No TP signature 5. In an interview on 10/29/30 at 13:30 p.m., TS 3 confirmed the above finding. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Coagulation proficiency testing (PT) result for 1 analyte in 2020. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the Technical Supervisor 3 (TS3) during a tour of the laboratory on 10/29/20 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) and College of American Pathologists (CAP) PT providers. 3. The laboratory received unacceptable PT result in the API 2020 Chemistry Core 1st event for the analyte listed below. Sample Test CM-04 D Dimer 4. Investigation of unacceptable results was required as established in the Proficiency Testing policy located in the Laboratory Policies & Procedures manual. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview on 10/29/30 at 13:30 p.m., TS 3 confirmed the above finding. .
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2018, one 2019 and one 2020 proficiency testing (PT) score when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology, Urinalyis, Parasitology and Chemistry testing as confirmed by the Technical Supervisor 3 (TS3) during a tour of the laboratory on 10/29/20 at 8:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) and College of American Pathologists (CAP) PT providers. 3. The following PT events / samples / test results were not graded by API due to lack of consensus. See below. Event Sample ID Analyte Heme / Coag BCI-10 Blood Cell ID 2018 / 2nd Heme / Coag US-02 Urine Sediment 2019 / 1st VKP-01 Vaginal Wet Prep (KOH) Chemistry Core CH-01 Creatinine 2020 / 1st 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summary for the above analytes were not present in laboratory records. Evaluation of the non-graded results were not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded results upon request. 5. In an interview on 10 /29/30 at 13:30 p.m., TS 3 confirmed the above finding .