

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D0398507	<b>(X3) Date Survey Completed</b> 08/30/2022
<b>Name of Provider or Supplier</b> Essentia Health Sandstone	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee and Testing Personnel failed to attest to the integration of proficiency testing samples into the routine patient workload on 1 of 16 occasions in 2021, and 4 of 9 occasions in 2022 . Findings are as follows: 1. The laboratory performed Hematology / Coagulation and Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory on 09/29/22 at 9:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) and College of American Pathologists (CAP) as 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 on-line (MediaLab) manual. 4. The Laboratory Director or designee and Testing Personnel failed to attest to the integration of PT samples into the routine patient workload for a total of 5 of 31 API &amp; CAP PT events reviewed in the November 2020 through September 2022 timeframe. See below. Event Specialty missing attestation 2021-3 API - Hematology / Coagulation (document not signed) 2022-A CAP - CGSA4 (document not signed) 2022-1 API - Chemistry Core (document not signed) 2022-2 API - Chemistry Core (document not signed) 2022-1 API - Chemistry Miscellaneous (document not signed) 5. In an interview on 09/29/22 at 1:05 p.m., the TS confirmed the above findings. .</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

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 two unacceptable proficiency testing (PT) results in 2021 and one unacceptable proficiency testing (PT) result in 2022. Findings are as follows: 1. The laboratory performed Microbiology and Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory on 09/29/22 at 9:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) as PT provider. 3. The laboratory received the following unacceptable PT results in 2021 and 2022. See below. 2021 Microbiology - 2nd event Sample: GS-06 Test: Gram Stain 2021 Hematology / Coagulation - 3rd event Sample: BFL-04 Test: RBC (Manual - CSF/BF) 2022 Chemistry Core - 2nd event Sample: CH-07 Test: Total Protein 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Policy located in the on-line (MediaLab) manual. 5. Investigation of the unacceptable PT results were not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview on 09/29/22 at 1:05 p.m., the TS confirmed the above findings. .

**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 non-graded non-regulated proficiency testing (PT) result in 2021 when the PT program did not obtain the agreement required for scoring, and failed to verify the accuracy of two non-regulated, and five regulated proficiency testing (PT) results when the laboratory received a zero score for non-participation in 2022 . Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory on 09/29 /22 at 9:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) as PT provider. 3. The laboratory failed to verify the accuracy of one non-graded non-regulated proficiency testing (PT) result in 2021 when the PT program did not obtain the agreement required for scoring. See below: 2021 Hematology / Coagulation - 3rd event Sample: YKP-03 Test: Vaginal Wet Prep (KOH) 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above sample was not present in laboratory records. An evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. The laboratory failed to verify the accuracy of two non-graded non-regulated, and five non-graded regulated proficiency testing (PT) results when the laboratory received a zero score for non-participation. See below:

2022 Microbiology - 2nd event Samples: GS-06 thru GS-10 Test: Gram Stain & Morphology 2022 Microbiology - 2nd event Samples: KOH-03 thru KOH-04 Test: KOH (Glass Slide) 6. The laboratory failed to submit results to API for seven PT samples prior to the submission deadline for the 2022 Microbiology second testing event. API assigned a zero score for failure to participate. 7. A self-evaluation of the seven results was not found during review. The laboratory was unable to provide a self-evaluation of the results upon request. 8. Evaluation of non-graded PT results was required as established in the Proficiency Testing Policy located in the on-line (MediaLab) manual. 9. In an interview on 09/29/22 at 1:05 p.m., the TS confirmed the above findings. .

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
. Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to review and evaluate proficiency testing (PT) results for 8 of 31 events reviewed. Findings are as follows: 1. The laboratory performed Immunology, Hematology / Coagulation, Chemistry and Microbiology testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory on 09/29/22 at 9:10 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) and College of American Pathologists (CAP) as PT providers. 3. The results of the following PT events were not reviewed or evaluated by the Laboratory Director or designee in the November 2020 through September 2022 timeframe: API 2021 Immunology - Immunohematology - 3rd Event. API 2021 Hematology - Coagulation - 3rd Event. CAP 2022 CGSA4 - Event "A" API 2022 Chemistry Core - 1st Event. API 2022 Chemistry Core - 2nd Event. API 2022 Chemistry Miscellaneous - 1st Event. 4. The laboratory was unable to provide these documents upon request. 5. In an interview on 09/29/22 at 1:05 p.m., the TS confirmed the above findings. .

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
. Based on a review of proficiency testing (PT) reports from the American Proficiency Institute and interviews with the Technical Supervisor, the Laboratory Director failed to provide overall management and direction in accordance with 493.1455 of this subpart. Findings are as follows: The Laboratory Director failed to attest to the

integration of PT samples into the routine patient workload . See D2009 The Laboratory Director failed to investigate unacceptable PT results. See D5211. The Laboratory Director failed to to verify the accuracy of PT results when the PT program did not obtain the agreement required for scoring and when the laboratory received a zero score for non-participation . See D5215. The Laboratory Director failed to review and evaluate proficiency testing (PT) results. See D6018. The Laboratory Director failed to ensure PT results were returned to the PT provider within the established timeframe. See D6090

**D6090**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:  
. Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API) and interviews with the Technical Supervisor, the Laboratory Director failed to ensure PT results were returned to API within the established timeframe. Findings include: 1. The laboratory failed to return their PT results to API prior to the submission deadline for the event listed below. 2022 Microbiology - 2nd event 2. In an interview on 09/29/22 at 1:05 p.m., the TS confirmed the above findings. .