

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0398507	(X3) Date Survey Completed 07/31/2018
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>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 a non-regulated Chemistry analyte at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/31/18 at 8:10 a.m. 2. Beta Hydroxybutyrate was added to the laboratory test menu on 03/15/17 as indicated in the performance verification records for the analyte and confirmed by the General Supervisor during the tour. 3. Twice annual verification of accuracy documents for Beta Hydroxybutyrate were not found during review of laboratory proficiency testing records from 2017 through date of survey, 07/31/18. The laboratory was unable to provide verification of accuracy documents upon request. 4. The laboratory was given an opportunity to provide the missing documents within 7 days from the survey date. 5. In an email received on 08/05/18 at 8:36 a.m., the TC confirmed the accuracy of Beta Hydroxybutyrate testing had not been verified in 2017 or 2018.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

. Based on observation and interview with laboratory personnel, the laboratory failed to label a secondary container used for gram staining. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/31/18 at 8:10 a.m. 2. One glass jar containing a dark liquid labeled "7/26/18" was observed in the gram staining area of the laboratory during the tour. A bottle of Gram Crystal Violet was adjacent to the glass jar. 3. In an interview on 07/31/18 at 8:15 a.m., the TC confirmed the jar was not labeled.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on observation, document review and interview with laboratory personnel, the laboratory failed to demonstrate two new analytes could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. In addition, the laboratory failed to verify the performance of laboratory test systems after relocating the laboratory to new location. Findings are as follows: The laboratory performed Microbiology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/31/18 at 8:10 a.m. A. Procalcitonin 1. An Abbott Architect i1000 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began Procalcitonin testing using this analyzer on 02/20/18 as indicated in the performance verification documents and confirmed by the General Supervisor during the tour. 2. Laboratory performance verification (PV) studies completed to verify the reportable range of Procalcitonin (PCT) did not reach the upper limits of the adopted reportable range for the analyte found in the Procalcitonin Architect 1 System procedure. See below. Analyte PV Adopted PCT 0.02-159.97 0.02-1000 3. In an interview on 07/31/18 at 2:05 p.m., the TC confirmed the laboratory's PV did not verify the upper limit of the adopted reportable ranges. B. Beta Hydroxybutyrate 1. An Abbott Architect c4000 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began Beta Hydroxybutyrate testing using this analyzer on 03/15/17 as indicated in the performance verification documents and confirmed by the General Supervisor during the tour. 2. Laboratory performance verification (PV) studies completed to verify the reportable range of Beta Hydroxybutyrate (BHB) did not reach the upper or lower limits of the adopted reportable range for the analyte found in the Beta Hydroxybutyrate Architect C System procedure. See below. Analyte PV Adopted BHB 0.06-9.50 0.0-11.81 3. Laboratory PV studies completed to verify the precision of BHB testing included testing of three levels of quality control material on one day, 10/28/16. Additional activities to verify precision were not

found. 4. In an interview on 07/31/18 at 2:10 p.m., the TC confirmed the laboratory's PV did not verify the upper and lower limits of the adopted reportable ranges and no further activities were performed to verify precision. C. Performance verification after relocation 1. The entire laboratory moved to a new location on 05/17/17 as indicated by the TC. 2. Documentation of PV studies performed on non-waived test systems to confirm the relocation did not affect test performance was not found in laboratory records. The laboratory was unable to provide relocation PV documentation upon request. 3. In an interview on 07/31/18 at 5:05 p.m., the TC stated performance verifications were completed after test systems were relocated but the records could not be located.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to ensure all training and initial competency assessments for 2 of 2 new testing personnel was documented. Findings are as follows: 1. The laboratory performed Hematology and Immunochemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 07/31/18 at 8:10 a.m. 2. Two testing personnel (TP) began employment with the laboratory since the previous survey in 2016. See below for month of hire. The General Supervisor (GS) confirmed at 8:45 a.m. on date of survey that both employees currently performed Hematology and Immunochemistry testing independently in the laboratory. TP Hired TP2 September 2017 TP3 January 2018 3. Documentation of all initial training and competency assessments for the two new employees was not found during review of laboratory records. See below for missing documents. The laboratory was unable to provide these documents upon request. TP Missing documents TP2 Coagulation, Immunochemistry TP3 Coagulation 4. In an interview on 07/31/18 at 9:35 a.m., the GS confirmed the above finding. The GS explained the missing initial training and competency assessment for TP2 and TP3 had been completed but could not be located.