Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651464	08/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Essentia Health Moose Lake	4572 Co Rd 61, Moose Lake, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain Hematology and Immunohematology quality control (QC) records and Hematology analyzer maintenance records for at least 2 years. Findings are as follows: 1. The laboratory performed Hematology (Coagulation) and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Stago STA Satellite analyzer and an Ortho MTS ID-Micro Typing System were observed as present and available for use during the tour. 3. The March 2017 QC records for the Stago STA Satellite and the February 2017 Stago Satellite Maintenance Chart were not present in laboratory records on date of survey. The laboratory was unable to provide the missing documents upon request. 4. The February 2017 Blood Bank Quality Control Record was not present in laboratory records on date of survey. The laboratory was unable to provide the missing document upon request. 5. The laboratory was given an opportunity to locate the missing QC and maintenance records and provide them to the surveyor within 7 days of the survey. 6. In an email message received on 09/07/18 at 1:12 p.m., the GS indicated the missing QC and maintenance records could not be located.
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 evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received unacceptable PT results from API in Microbiology, Chemistry, and Hematology as listed below. Event Sample Test Lab API result 2017-1 BFL-02 Mono* 50 0-42 2017-1 BFL-02 PMN* 50 54-100 2017-1 XE-03 Neut* 42.5 35.0-41.8 2017-2 CH-06 HCG* 858 871-1052 2017-2 UR-06 MIC* Int* Susceptible 2017-3 CH-14 Ph* 2.3 1.7-2.1 2017-3 UR-11 MIC Int Resistant 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 08/29/18 at 4:30 p.m., the GS confirmed a documented evaluation of the unacceptable results was not performed. * Note Mono - Mononuclear cell count PMN - Polymorphonuclear cell count Neut - Neutrophil HCG - Human Chorionic Gonadotropin MIC - Micro-organism Susceptibility Ph - Phosphorous Int - Intermediate
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. 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 non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Microbiology, Hematology and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API due to no consensus in Microbiology, Hematology and Immunohematology for the events and tests listed below. The Data Summaries from API with the expected results for these tests were not included in the laboratory's records. Event Sample ID Test 2016-3 UA-05 Urobilinogen 2016-3 UA-06 Urobilinogen 2016-3 UR-11 Urine Identification 2017-2 UA-03 Urobilinogen 2017-2 UR-06 Susceptibility 2017-3 DAT-04 Direct Antiglobulin Testing 2018-1 BFL-01 Polymorphonuclear cell count 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide evaluations upon request. 5. In an interview on 08/29/18 at 4:30 p.m., the GS confirmed an evaluation of the non-graded PT results was not performed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to include Hematology reference intervals (normal values) in the procedure manual (10). Findings are as follows: 1. The laboratory performed Hematology (Coagulation) testing as confirmed by the General Supervisor (GS)) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Stago STA Satellite analyzer and a Streck ESR Auto Plus analyzer were observed as present and available for use during the tour. The GS indicated International Normalized Ratio (INR) results were obtained from testing performed on the STA Satellite and Erythrocyte Sedimentation Rate (ESR) testing was performed on the ESR Auto Plus. 3. Normal values for INR and ESR testing were not present in Hematology procedures located in the PolicyTech online procedure manual. 4. In an interview on 08/30/18 at 10:48 a.m., the GS confirmed the INR and ESR reference ranges were not included in procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with laboratory personnel, the laboratory failed to ensure Histopathology testing materials were not used after the expiration date had been exceeded. Findings are as follows: 1. Frozen section evaluations were performed in the laboratory under the subspecialty of Histopathology as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. Expired stains and reagents were observed as present and available for use during the tour of the laboratory. See below. Item Lot Exp. date Eosin 204745 10/2013 Eosin 225612 04/2015 Hematoxylin 255780 10/2014 Hematoxylin 199391 02/2013 Formalin 240837 11/2016 Xylene 226029 05/2014 3. In an interview on 08/29/18 at 1: 15 p.m., the GS confirmed the above materials were available for use after the expiration date had been exceeded.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review, observation and interview with laboratory personnel, the laboratory failed to perform quality control activities as established in an Individualized Quality Control Plan (IQCP) for Chemistry testing. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. An Abbott i-STAT hand-held analyzer was observed as present and available for use during the tour. The GS indicated blood gas testing was performed on this analyzer. 3. i-STAT quality control (QC) performance was required with every new lot or shipment and every 30 day as established in the laboratory's IQCP for the analyzer. 4. The time interval between i-STAT QC performance exceeded that established in the IQCP on 1 occasion between 11/08/17 and 04/08/18. See below QC date QC date Interval 02/12 /18 04/08/18 56 days 5. In an interview on 08/30/18 at 11:26 a.m., the GS confirmed the i-STAT QC had not been performed as required in the IQCP. In an email received on 09/07/18 at 10:57 a.m., the GS indicated 4 patient samples were tested on the Abbott i-STAT between 03/12/18 and 04/07/18
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory staff, the laboratory failed to perform and document positive and negative Gram stain quality control performance each week of patient testing. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Gram Staining set-up was observed as present and available for use during the tour. 3. Weekly Gram Stain quality control (QC) frequency requirements were established in the Microbiology Quality Control Procedure located in the online PolicyTech procedure manual. 4. Gram Stain weekly QC was not performed or documented for 3 of 13 weeks during the time period of April 2018 - June 2018 as indicated on the Microbiology Maintenance Form . 5. In an interview on 08/30/18 at 12:10 p.m., the GS confirmed the above finding.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)

	(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to perform and document Immunohematology quality control) QC) activities each day of patient testing. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. An Ortho MTS ID-Micro Typing System was observed as present and available for use during the tour. 3. Review of blood bank patient test logs and QC records from July 2017 - December 2017 revealed four days of patient testing when QC was not documented which potentially affected 10 patients. See below. QC activities were not documented on 1 of 15 days of patient testing in August, 2 of 22 days of patient testing in September, and 1 of 23 days of patient testing in November. Date Patients 08/11/17 3 09/08/17 3 09/09/18 2 11/06/17 2 4. In an interview on 08/30/18 at 12:45 p.m., the GS confirmed there was no evidence that quality control testing was performed on the four days of patient testing listed above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with the laboratory personnel, the laboratory failed to ensure the packed red cells stored in the transfusion service area were maintained between 1 - 6 degrees centigrade at all times. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Helmer Blood Bank refrigerator with a continuous temperature monitoring chart was observed in use during the tour. 3. Two of twenty four weekly temperature charts reviewed failed to include continuous recording of temperatures. See below: - Dates on the chart: 06/29/17 - 07/06/17 No recording over the entire period. - Dates on the chart: 09/21/17 - 09/28/17 Stylus stopped recording on Thursday between 12:00 a.m. to 6:00 a.m. 4. Documentation of review or action taken was not found for the gaps in temperature recording noted above. 5. In an interview on 08/30/18 at 12:20 p.m., the GS confirmed the above findings.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure the final test result date was indicated on the test report (c)(3). Findings are as follows: 1. The laboratory performed Microbiology testing as by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Microbiology Urine Culture patient test report reviewed on date of survey did not indicate the final test result date. 3. In an interview on 08/30/18 at 12:10 p.m., the GS confirmed the final test result date was not included on the test report.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure a reference interval was included on a patient test report. Findings are as follows: 1. The laboratory performed Hematology (Coagulation) testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. A Stago STA Satellite analyzer was observed as present and available for use during the tour. The GS indicated INR results were obtained from testing performed on this analyzer 3. Reference intervals for INR results were not included on the patient test report from 02/09/17 reviewed on date of survey. 4. In an interview on 08/30/18 at 10:45 a.m., the GS confirmed INR reference ranges were not included on the patient test report.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical supervisor failed to evaluate 1 of 4 testing personnel for Microbiology, Chemistry, and Immunohematology test procedure competency in 2017. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Immunohematology testing in 2017 as confirmed by the General Supervisor (GS) during a tour of the laboratory on 08/29/18 at 1:10 p.m. 2. Review of competency assessment documents did not indicate the GS was evaluated for test procedure competency in 2017 as listed below. Specialty Missing competency assessments Microbiology Gram stain only Chemistry All (Architect) Immunohematology All 3. The laboratory was unable to provide documentation of these competency evaluations upon request. 4. In an interview on 08/29/18 at 2:25 p.m., the GS confirmed the above finding.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate problem solving skills during annual competency assessments for 4 of 4 testing personnel in 2017. Findings are as follows: 1. The Yearly Competency Policy and Procedure located in the online procedure manual PolicyTech included a requirement to evaluate problem solving skills during annual competency assessments. 2. Review of competency assessment documents did not provide evidence that problem solving skills were evaluated for 4 of 4 testing personnel during annual competency assessments in 2017. 3. In an interview on 08/29/18 at 2:40 p.m., the General Supervisor confirmed evaluation of problem solving skills was not evaluated during annual competency assessments.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on review of education documents and interview with laboratory personnel, the laboratory failed to ensure personnel performing high complexity testing meet the qualification requirements of 493.1489. Findings are as follows: The laboratory failed to ensure all testing personnel met the qualification criteria to perform high complexity testing. See D6171 The performance of testing procedures by unqualified personnel constitutes Condition- level noncompliance. The laboratory performed approximately 104,265 tests on patient specimens annually.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of

osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

	. Based on document review and interview with laboratory personnel, the laboratory failed to obtain an equivalency evaluation of foreign education credentials for 1 testing personnel. Findings are as follows: 1. Testing Personnel 4 (TP4) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing high complexity testing on patient specimens. Laboratory records indicated TP4 began training in the laboratory on 06/19/18. 2. Education credentials found in personnel records indicated TP4's education was obtained at the University of San Agustin, Iloilo, Philippines. 3. An equivalency evaluation of foreign credentials was not found in personnel records. The laboratory was unable to provide an equivalency evaluation upon request. 4. In an interview on 08/29/18 at 2:20 p.m., the General Supervisor confirmed an equivalency evaluation of TP4's foreign education credentials had not been obtained. .