Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0651464	08/02/2022
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of one performance verifications reviewed from 2020 was approved, signed, and dated by the laboratory director prior to implementation. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by the General Supervisor during a tour of the laboratory at 8:05 a.m. on 07/27/22. 2. Cardinal Health hCG Combo test kits were observed as present and available for use during the tour of the laboratory. 3. A performance verification (PV) for the Cardinal Health hCG Combo test kit, found in the Cardinal HCG folder, was reviewed on date of survey. 4. The laboratory director's approval signature and date were not found in the PV documents. 5. The laboratory performed serum hCG testing on 45 patients since implementation in December 2020 as indicated by the Technical Consultant (TC) on date of survey. 6. In an interview at 1:10 p.m. on 07/27 /22, the TC confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities required for a Microbiology test system. Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 07/27/22. 2. A Cepheid GeneXpert System was observed as present and available for use during the tour. The GS stated the MRSA assay was implemented on this system on 06/21/22. 3. Quality control (QC) testing with positive and negative control materials was required with each new lot and shipment and monthly as indicated in the Cepheid MRSA procedure located in the Healthcare Platform MediaLab 4. The laboratory's records indicated QC was performed on 06/15 /22 and 07/24/22. 5. The laboratory did not establish an Individual Quality Control Plan to reduce the frequency of QC performance from 2 levels of control material each day of patient testing. 6. Testing records from the analyzer indicated nine patients received MRSA testing without daily QC since 06/21/24. See below. Date Patients tested 06/23/22 1 06/24/22 1 06/29/22 1 07/04/22 1 07/14/22 1 07/17/22 1 07 /18/22 1 07/19/22 1 07/23/22 1 7. In an interview at 3:25 p.m. on 07/27/22, the GS confirmed the above finding. .
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 laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator in 2022 with the frequency defined by the laboratory. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on at 8:05 a. m. on 07/27/22. 2. The laboratory stored blood products in a designated refrigerator. The blood storage refrigerator had a temperature alarm system. 3. Quarterly blood product storage alarm check requirements were established by the laboratory. 4. Blood product storage alarm checks for 2022 were not found during review of laboratory records. 5. The laboratory provided Immunohematology results to approximately 252 patients annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 4:50 p.m. on 07/27/22, the GS confirmed the above finding. 7. The laboratory was given five days to provide documentation of alarm checks completed in 2022. In an email received on 08/02/22 at 7:22 a.m., the GS indicated no alarm checks had been completed in 2022. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)

	(b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to ensure training for two of two new testing personnel was performed and documented in 2021. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor during a tour of the laboratory at 8:05 a.m. on 07/27/22. 2. The Hologic TLilQ, Sysmex XS-10001 and STA Stago Satellite analyzers were present and available for use during the tour. 3. Initial training was required for new testing personnel as established in the Training and Competency Policy found in the found in the Healthcare Platform MediaLab. 4. Testing Personnel 4 (TP4) began laboratory training in May 2021 and Testing Personnel 5 (TP5) began laboratory training in December 2021 as indicated in MediaLab competency assessment reports. 5. Initial training reports for TP4 and TP5 were not found during review of MediaLab as indicated below. TP4 - Hologic TLilQ, Sysmex XS-10001 and STA Stago Satellite TP5 - Hologic TLilQ and Sysmex XS-10001 6. The laboratory was unable to provide the missing training records upon request. 7. In an interview at 10:30 am., the Technical Consultant confirmed the above finding. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of two testing personnel hired in 2021. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and General Immunology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 07/27/22. 2. The Abbott Architect and STA Stago Satellite analyzers and Mono II manual test kits were present and available for use during the tour. 3. Competency evaluations were required semi-annually for new testing personnel as established in the Training and Competency Policy found in the Healthcare Platform MediaLab. 4. Initial training was performed and documented for Testing Personnel 4 (TP4) on the Abbott Architect and Mono test kits in December 2021 as indicated in MediaLab competency assessment reports. Initial training documentation for TP4 was not found for the Stago Satellite analyzer - see D6045. 5. Semi-annual competency assessment reports for TP4 were not found for the Abbott Architect, the Stago Satellite, and the Mono test kits during review of MediaLab reports 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 10:30 a.m. on 07/27/22, the Technical Consultant confirmed the above finding. .

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least annually for four of four tenured testing personnel in 2021. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 07/27/22. 2. The Hologic TLilQ, Sysmex XS-10001, and STA Stago Satellite analyzers were present and available for use during the tour. 3. Annual competency assessments were required as established in the Training and Competency Policy found in the found in the Healthcare Platform MediaLab. 4. Annual competency assessment reports for the following testing personnel (TP) were not found during review of MediaLab as indicated below. GS - Hologic TLilQ, Sysmex XS-10001, and STA Stago Satellite TP1- Hologic TLilQ, and Sysmex XS-10001 TP2- Hologic TLilQ, and Sysmex XS-10001 TP3- Hologic TLilQ, and Sysmex XS-10001 6. The laboratory was unable to provide the missing records upon request. 7. In an interview at 10:30 am. on 07/27/22, the Technical Consultant confirmed the above finding. .