Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0040859	12/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Health	515 5th Avenue W, Grand Marais, 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
D0000	The North Shore Health laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial survey performed on December 20, 2023, and December 21, 2023. The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1253 Establishment and verification of performance specifications 493.1256 Control Procedures .
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 director failed to approve two written procedures in use by the laboratory in 2023. 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 1:15 p..m. on 12/20/23. 2. A Cobas e411 chemistry analyzer and a Sysmex XS-1000 hematology analyzer were observed as present and available for use during the tour. 3. Laboratory Director approval of the following procedures was not found during review on date of survey: e411 B-HCG procedure, located in the Cobas e411 Procedure Manual Complete Blood Count Sysmex XS-1000 procedure located in the Hematology Procedure Manual 4. In interviews at 1:50 p.m. and 2:25 p.m. on 12 /21/23, the GS confirmed the above finding. .
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 complete the reportable range verification and reference interval verification for two of two non-waived test systems implemented by the laboratory since August 2023. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:15 p..m. on 12/20/23. A. Chemistry 1. An Abbott i-STAT analyzer was observed as present and available for use during the tour of the laboratory. A back-up Basic Metabolic Panel using the CHEM 8+ cartridge on this analyzer was approved for use on 09/21/23 as confirmed by laboratory records. The CHEM 8+ cartridge included eight analytes. 2. Reference interval and reportable range verification documentation for the eight analytes in the CHEM 8+ cartridge was not found during review of the performance verification documentation located in the Chem 8 Correlation folder. The laboratory was unable to provide CHEM 8+ analyte reference interval and reportable range verifications upon request. 3. The laboratory had not performed any testing using the CHEM 8+ cartridge on the i-STAT analyzer since implementation through date of survey as indicated by internal reports generated by the GS. 4. In an interview at 9:10 a.m. on 12/21/23, the GS confirmed the above finding. B. Hematology 1. An Alcor MiniiSED analyzer was observed as present and available for use during the tour of the laboratory. Erythrocyte Sedimentation Rate (ESR) testing using this analyzer was implemented on 10/17/23 as indicated by the GS and confirmed in laboratory records. 2. Reference interval verification documentation for ESR testing on the MiniiSED analyzer was not found during review of the performance verification (PV) documentation located in the ERS - MiniiSED Validation folder. The laboratory was unable to provide ESR reference interval verification upon request. 3. The ESR upper reportable range limit adopted by the laboratory did not reflect the actual reportable range value obtained by the laboratory during the PV as indicated in laboratory documents. See below. Analyte PV Adopted ESR 0-74 1-130 4. The laboratory performed ESR testing on 96 patient samples since implementation as indicated by an internal report generated by the GS on date of survey. 5. In an interview at 9:10 a.m. on 12/21/23, the GS 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 Bacteriology media and Virology testing in 2023. Findings are as follows: The laboratory performed Bacteriology and Virology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:15 p.m. on 12/20/23. A. Bacteriology 1. A bioMrieux BacT/ALERT 3D Microbial Identification System was observed as present and available for use during the tour. The laboratory performed Blood Culture microbial detection using the BacT/ALERT system . 2. Quality Control (QC) requirements for the BacT/ALERT culture media were not found in the Blood Cultures BacT/Alert 3D Microbial ID System procedure located in the Blood Culture - BacT/Alert 3D Microbial ID System manual. The laboratory was using the manufacturer's Certificate of Conformance as QC. 3. A BacT/ALERT culture media Individual Quality Control Plan (IQCP) to reduce the frequency of required QC performance for media sterility, ability to support growth, and visual appearance before or concurrent with use was not found in laboratory records. The laboratory was unable to provide an IQCP for the BacT/ALERT culture media upon request. 4. The laboratory performed 71 Blood Culture microbial detection tests since 08/01/23 as indicated in an internal report generated by the GS on date of survey. 5. In an interview at 3:45 p.m. on 12/21/23, the GS confirmed the above finding. B. Virology 1. A Cepheid GeneXpert Molecular Diagnostic Testing System was observed as present and available for use during the tour. The laboratory performed testing for SARS-CoV-2, Influenza A and B, and Respiratory Syncytial Virus (4-Plex) using this system. 2. Quality Control (QC) testing with positive and negative QC material was required for new lots and shipments of 4-Plex testing materials as established in the SARS-CoV-2 (COVID-19), Influenza A&B, & RSV by Cepheid 4-Plex Plus PCR procedure located in the GeneXpert IV manual. 3. A 4-Plex Individual Quality Control Plan (IQCP) to reduce the frequency of required QC performance from each day of patient testing was not found in laboratory records. The laboratory was unable to provide an IQCP for the 4-Plex test upon request. 4. The laboratory performed 215 4-Plex tests since 08/01/23 as indicated in a internal reports generated by the GS on date of survey. 5. In an interview at 4:10 p.m. on 12/21/23, the GS confirmed the above finding. .