Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403658	11/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ely Bloomenson Community Hospital	328 West Conan Street, Ely, 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
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 a new chemistry analyzer could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/15/18 at 8:05 a.m. 2. A Siemens Dimension EXL 200 chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began chemistry testing using this analyzer on 05/31/18 as indicated in the performance verification documents and confirmed by laboratory personnel during the tour. 2. Laboratory performance verification (PV) studies completed to verify the reportable range of the analytes below did not reach the upper or lower limits of the reportable range adopted by the laboratory. See below. Analyte PV Adopted Amylase 16.67-755.33 0.00-650.00 AST* 9.00-832 0-800 Calcium 7.40-13.10 0-14 CRP* 0.367-11.13 0.20-12.00 Potassium 1.40-9.57 1.00-10.00 Sodium 66.33-187.67 50.0-200.0 Protein(urine/CSF*) 8.30-259.73 6.00-250.00 3. In an interview on 11/15/18/18 at 2:20 p.m., the GS confirmed the laboratory's PV did not verify the upper or lower limit of the above adopted reportable ranges. *Note AST - aspartate aminotransferase CRP - C-Reactive Protein CSF - Cerebral Spinal Fluid

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a system to ensure manually entered test results were entered accurately and reliably. Findings are as follows: 1. The laboratory manually entered test results from non-interfaced test systems into the Epic/Beaker laboratory information system. 2. A procedure to verify the accuracy of this manual entry was not found during a review of the laboratory's written procedure manuals. 3. In an interview on 11/16/18, at 12:15 p.m. the General Supervisor confirmed a process to verify the accuracy of manually entered results had not been established.
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 reference intervals were consistent between Chemistry procedures and patient test reports. Findings are as follows: The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 11/15/18 at 8:05 a.m. A. Abbott I-STAT 1. An Abbott i-STAT System analyzer was observed as present and available for use during the tour. 2. A reference interval listed in the I-STAT 300 procedure was not consistent with those included on the patient test report reviewed on date of survey as indicated below. Patient - adult tested on 05/22/18 Analyte* Procedure Report SO2 95-98 95-100 3. In an interview on 11/16/18 at 10:15 a.m., the GS confirmed the reference range discrepancy between the procedure and the patient test report. B. Siemens Dimension EXL 200 1. A Siemens Dimension EXL 200 chemistry analyzer was observed as present and available for use during the tour. 2. The reference intervals listed in the E-BCH Chemistry Department Ranges chart were not consistent with those included on the patient test report reviewed on date of survey as indicated below. Patient - adult female tested on 09/25/18 Analyte Chart Report Sodium 136-145 134-143 Potassium 3.5-5.1 3.3-4.6 3. In an interview on 11/16/18 at 10:36 a.m., the GS confirmed the reference range discrepancies between the chart and the patient test report. *Note SO2 - Oxygen Saturation