Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403629	08/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Hospital	512 Skyline Blvd, Cloquet, 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 Community Memorial Hospital 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 recertification survey performed on July 31, 2024 and August 1, 2024. The following standard-level deficiencies were cited: 493.1253 Establishment and verification of performance specifications 493.1256 Control Procedures 493.1445 Laboratory director responsibilities 493.1451 Technical supervisor responsibilities .
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 ensure 11 of 11 Chemistry reportable ranges obtained during one of three performance verifications (PV) completed in 2024 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by General Supervisor 2 (GS2) during a tour of the laboratory at 12:40 p.m. on 07/31/24. 2. A Siemens Healthineers RAPIDPoint 500e Blood Gas System was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer to perform testing on 06/03/24. 3. PV activities were completed in April 2024 as indicted in records found in the RP500e Validation /Training manual. The Laboratory Director approved the PV on 07/29/24. 4. The

	laboratory's Overall Quality System Design policy found in the Laboratory Quality Manual indicated the reportable range must be adjusted to that which can be proven on Community Memorial Hospital's analyzers. 5. The upper and/or lower reportable range limits adopted by the laboratory for 11 of 11 analytes did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in Performance Summary documents found in the RP500e Validation/Training manual . See below. Analyte Obtained Adopted pH 6.709-7.718 6.500-7.800 Carbon Dioxide 15.7-159.9 5.0-200.0 Oxygen 45.4-523.3 10.0-700.0 Sodium 110.7-171.3 100.0-200.0 Potassium 1.42-11.46 0.50-15.00 Chloride 73.0-126.0 65.0-140.0 Glucose 25.7-686.3 20.0-750.0 Lactate 4.41-177.21 1.60-270.30 Total Hemoglobin 5.0-21.2 2.0-25.0 Total Carbon Dioxide 4.3-32.1 5.0-50.0 Urea Nitrogen 4.0-108.0 3.0-120.0 6. In an interview on 08/01/24 at 12:50 p.m. and 1:15 p.m., GS2 confirmed the above finding and indicated the manufacturer's analytical measuring range for the analytes had been adopted. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 document Hematology quality control procedures performed to evaluate stain for intended reactivity each day of use from August 2022 through July 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed by General Supervisor 2 (GS2) during a tour of the laboratory at 12:40 p.m. on 07/31/24. 2. Manual differential stains and a Zeiss Axiolab 5 microscope used to perform manual differentials were observed as present and available for use during the tour. 3. The Manual Differential on Peripheral Blood procedure found in the Hematology Dept Procedures manual included direction to determine overall staining quality but did not include direction to document this activity for manual differentials. 4. Hematology testing for patient MRN# xxx591, which included a manual differential performed on 01/31/23, was reviewed on date of survey. Documentation of acceptable stain intended reactivity was not found for the day of patient testing. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 4:05 p.m on 08/01/24, GS2 confirmed the above finding and stated the laboratory did not document the quality of staining when performing a manual differential. .
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure all testing personnel were evaluated for test procedure competency as required. Findings are as follows: 1. The laboratory was cited for non-performance of initial competency evaluations during the three previous surveys conducted on 08/10/22, 11/05/20, and 07/18/18. 2. Initial competency evaluations were found incomplete on date of current survey, 07/31/24, for three of six new testing personnel hired in 2023. See D6120. 3. In an interview at 3:55 p.m. on 07/31 /24, General Supervisor 2 confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to ensure initial competency assessment for three of six new testing personnel was performed and documented in 2023. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by General Supervisor 2 (GS2) during a tour of the laboratory at 12:40 p.m. on 07/31/24. 2. The following test systems and test kits were observed as present and available for use during the tour: Alcor miniiSED ESR analyzer Qiagen Amnisure ROM Test kit Abbott BinaxNOW Streptococcus pneumoniae test kit Abbott BinaxNOW Legionella test kit OSOM hCG Combo Test kit 3. Initial competency assessment was required for new testing personnel as established in the Competency Assessment procedure found in the Laboratory Quality Manual. 4. Initial competency assessment documentation for the Alcor MiniiSED analyzer was not found during review of personnel records for the following testing personnel (TP): TP6, TP7, TP8. Initial competency assessment documentation for the Amnisure, Streptococcus pneumoniae, Legionella, and hCG test kits was not found during review of personnel records for TP8. 5. The laboratory was unable to provide the missing competency assessment records upon request. 6. In an interview at 3:55 p.m. on 07/31/24, GS2 confirmed the above finding. 7. This issue was previously cited during the 08/10/22, 11/05/20, and 07/18/18 surveys. See D6103 .