

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403629	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Community Memorial Hospital	Street Address, City, State 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 August 5, 2026 and August 6, 2026. The following condition-level deficiency was cited: 493.801 Testing of proficiency testing samples The following standard-level deficiencies were cited: 493.1105 Retention requirements 493.1256 Control procedures 493.1451 Technical supervisor responsibilities .
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to enroll in an HHS approved proficiency testing (PT) program as required under 493.801 for microscopic Hematology testing performed in 2025 and 2026. This failure has been deemed a Condition level deficiency. Findings are as follows: 1. The laboratory performed Hematology high complexity manual differential microscopy in 2025 and 2026 as indicated in the laboratory test menu provided by the Technical Supervisor (TS) prior to survey and confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:05 p.m. on 08/05/26. 2. The laboratory performed PT using the College of American Pathologists (CAP) provider. 3. The laboratory

	used CAP package VPBS Virtual Peripheral Blood Smear as PT for manual differential testing. The VPBS package included 15 blood cell identification educational challenges each event and was successfully performed twice annually in 2025 and 2026. 4. The laboratory failed to enroll in CAP PT package BCP Blood Cell ID, Photographs or BCPV Blood Cell Identification, Virtual as required to meet the regulatory requirement of three testing events annually with a minimum of 5 testing challenges per event. 5. In an interview at 10:05 a.m. on 08/06/26, the TS confirmed the above finding. .
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. In addition, retain the following: This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain thermometer calibration records from 2025 for at least 2 years. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:05 p.m. on 08/05/26. 2. Calibrated thermometers were observed in use in all temperature controlled devices (refrigerators, freezers, and various other equipment) during the tour of the laboratory. Reagents, quality control and calibration materials, media, blood products, and patient samples were stored in the temperature controlled devices. 3. Annual thermometer calibration checks were required as established in the CMH Laboratory Maintenance and Performance Verification procedure found in the Laboratory Equipment Performance and Maintenance manual. 4. The 2025 Calibrated Thermometer Check form was not found in laboratory records. The laboratory was unable to provide the missing document upon request. 5. In an interview at 1:15 p.m. on 09/13/24, the TC confirmed the above finding and indicated the 2025 thermometer calibration checks had been completed but laboratory staff were unable to locate the Calibrated Thermometer Check form. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: 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 (QC) activities required for Bacteriology media in 2025 and 2026. Findings are as follows: 1. The laboratory performed Bacteriology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:05 p.m. on 08/05/26. 2. A bioMrieux BacT/ALERT 3D microbial detection system, a Beckman Coulter DxM MicroScan WalkAway bacterial identification and antibiotic susceptibility testing system, and culture media were observed as present and available for use during the tour. 3. The laboratory retained the manufacturer's Certificate of Conformance and performed appearance checks on BAP, MAC, CNA, CDC ANA BAP, THIO, BRUCELLA W/H &K culture media upon receipt as indicated in the Quality Control for Commercially Prepared Media procedure located in the Microbiology Procedure book. 4. A culture media Individual Quality Control Plan (IQCP) to reduce the frequency of required QC performance for media sterility and ability to support growth before or concurrent with use for the above media was not found in laboratory records. The laboratory was unable to provide an IQCP for the culture media upon request. 5. In an interview at 4:15 p.m. on 08/06/26, the Technical Supervisor confirmed the above finding. .

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(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; (b)(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 comprehensive competency assessments for one of eleven tenured testing personnel were performed and documented in 2024 and 2025. Findings are as follows: 1. The laboratory performed Microbiology, Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 1:05 p.m. on 08/05/26. 2. The following non-waived test systems, analyzers, tests, and test kits were in use in 2023 as indicated by the GS during the tour: Beckman Coulter MicroScan DXM microbiology instrument bioMrieux BacT-ALERT microbiology instrument BioFire Film Array System microbiology instrument Ortho Vitros 7600 chemistry analyzer Siemens RapidPoint 500e Blood Gas System Profile-V MEDTOXScan chemistry analyzer Alere Triage Meter chemistry analyzer Alere Afinion2 chemistry analyzer Siemens EPOC blood analysis system Sysmex XN-1000 hematology analyzer Alcor miniiSED ESR analyzer Ortho Workstation Immunohematology test system Microscopes and stains for microscopic examinations Gram stain Manual differential Urine sediment Vaginal wet preparation Test kits Alere Quik Chek Clostridioides difficile Alere Quik Chek Giardia/Cryptosporidium Binax Now Legionella Binax Now Streptococcus pneumoniae BD BBL Streptococcus Antigen typing Chem Bio HIV 1/2 OSOM serum hCG Qiagen Amnisure 3. A competency assessment including all current laboratory tests was required annually for tenured testing personnel as established in the Competency Assessment procedure found in the Laboratory Quality Manual. 4. Competency assessment forms for the above non-waived test systems were not found for the tenured TC in 2024 and 2025 laboratory records. 5. The laboratory was unable to provide the missing competency assessment documentation upon request. 6. In an interview at 4:25 p.m. on 08/05/26, the TC

confirmed the above finding and indicated she occasionally performed testing on patient samples in 2024 and 2025. *Incomplete competency assessment performance was previously cited during the 08/01/24, 08/10/22, 11/05/20, and 07/18/18 surveys.*
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