

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403629	(X3) Date Survey Completed 07/24/2025
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 an off-site proficiency testing referral complaint investigation performed on July 24, 2025. The following condition-level deficiency was cited: 493.801 Enrollment and testing of samples .
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory engaged in proficiency testing referral in 2025. Findings are as follows: 1. The laboratory engaged in inter-laboratory communication regarding five hematology proficiency testing (PT) samples prior to the PT event submission deadline in February 2025. See D2012 2. The laboratory improperly submitted five hematology proficiency testing (PT) samples to another laboratory prior to the PT event submission deadline in February 2025. See D2013 .</p>
D2012	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage</p>

in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory engaged in inter-laboratory communication regarding five hematology proficiency testing (PT) samples prior to the PT event submission deadline in February 2025. Findings are as follows: 1. The Community Memorial Hospital laboratory (Lab A) performed proficiency testing using the College of American Pathologists (CAP) proficiency testing provider. 2. Sysmex XP-300 hematology test reports and additional documentation found in another laboratory's (Lab B) 2025 CAP Proficiency Test manual indicated Lab A sent five CAP hematology PT package FH9-A 2025 samples to Lab B on 02/11/25. See D2013 3. The result submission deadline for the FH9-A PT 2025 package was 02/12/25 as indicated on the CAP FH9-A Hematology Automated Differential Survey Result Form provided by General Supervisor 2. 4. The laboratory prohibited inter-laboratory communication pertaining to PT testing events as established in the Proficiency Testing Process procedure located in the Laboratory Quality Manual. 5. General Supervisor 2 (GS2) at Lab A was also Technical Consultant 2 at Lab B. GS2 was aware of the FH9-A PT 2025 results obtained for the five samples at Lab A when she brought the samples to Lab B for testing on 02/11/25. This constitutes inter-laboratory communication. 6. In an interview at 12:20 p.m. on 07/08/25, GS1 and GS2 confirmed the above finding. .

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

(b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory improperly submitted five hematology proficiency testing (PT) samples to another laboratory prior to the PT event submission deadline in February 2025. Findings are

as follows: 1. The Community Memorial Hospital laboratory (Lab A) performed proficiency testing using the College of American Pathologists (CAP) proficiency testing provider. 2. Sysmex XP-300 hematology analyzer test reports and additional PT documentation found in another laboratory's (Lab B) 2025 CAP Proficiency Test manual indicated Lab A sent five CAP hematology PT package FH9-A 2025 samples to Lab B on 02/11/25. Five test reports dated 02/11/25 for samples #1, #2, FH9-03, FH9-04, FH9-05 found at Lab B included handwritten documentation "FH9-A Hospital XN survey run at clinic". In addition, hand written documentation on Lab B's CAP FH13-A 2025 evaluation report dated 3/20/25 indicated "FH9-A survey from the hospital was run at clinic to compare Sysmex to Sysmex and study done". 3. The result submission deadline for the FH9-A PT 2025 package was 02/12/25 as indicated on the CAP FH9-A Hematology Automated Differential Survey Result Form provided by General Supervisor 2 (GS2). 4. The laboratory prohibited inter-laboratory communication pertaining to PT testing events as established in the Proficiency Testing Process procedure located in the Laboratory Quality Manual. 5. In an interview at 12:20 p.m. on 07/08/25, GS1 and GS2 confirmed the above finding. .