

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403641	(X3) Date Survey Completed 07/08/2025
Name of Provider or Supplier Cmh Raiter Family Clinic	Street Address, City, State 417 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
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 performed testing on five hematology proficiency testing (PT) samples obtained from another laboratory prior to the PT event submission deadline. Refer to D2012. .</p>
D2012	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage 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.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, document review, and interview with laboratory personnel, the laboratory performed testing on five hematology proficiency testing (PT) samples obtained from another laboratory prior to the PT event submission deadline in February 2025. Findings are as follows: 1. The laboratory performed hematology testing as indicated by Technical Consultant 1 (TC1) during a tour of the laboratory at 11:00 a.m. on 07/08/25. A Sysmex XP-300 hematology analyzer was observed as present and in use during the tour. 2. The laboratory performed proficiency testing using the College of American Pathologists (CAP) proficiency testing provider. 3. 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. 4. Documents found in the 2025 CAP Proficiency Test manual indicated the laboratory ordered CAP hematology PT package FH13 for the 2025 calendar year. Upon receipt of the FH13-A 2025 event samples, Technical Consultant 2 (TC2) discovered they had ordered the incorrect package per documentation observed on the CAP FH13-A 2025 Original Evaluation form. 5. Documentation indicated the laboratory tested the FH13-A samples and submitted the results per standard and acceptable protocol. 6. Sysmex XP-300 hematology test reports and additional documentation found in the CAP Proficiency Testing manual indicated the laboratory obtained and tested five CAP hematology PT package FH9-A 2025 samples from another laboratory on 02/11/25. 7. 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 the General Supervisor from the other laboratory. 8. Testing FH9-A 2025 PT samples obtained from another laboratory prior to the submission deadline constitutes inter-laboratory communication. 9. In an interview at 12:20 p.m. on 07/08/25, TC1 and TC2 confirmed the above finding.