

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405562	(X3) Date Survey Completed 01/27/2025
Name of Provider or Supplier Ccm Health	Street Address, City, State 824 North 11th St, Montevideo, 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	<p>. The CCM Health Montevideo 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 January 23 and 24, 2025. 493.1253 Establishment and Verification of Performance Specifications 493.1281 Comparison of Test Results .</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete required performance (PV) activities for one of two new analyzers or devices implemented by the laboratory in 2024. Findings are as follows: 1. The laboratory performed Coagulation testing under the Hematology Specialty as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 12:05 PM on 01/23/2025. 2. A Werfen IL ACL Top 350 Coagulation analyzer was observed as present and available for use during the tour. The laboratory performed D-Dimer and Anti-Xa testing using this analyzer beginning on 02/16/24. 3. PV documentation for Coagulation testing on the Werfen IL ACL Top 350 analyzer found in the Hemostasis Performance Verification Manual included accuracy, precision, and reportable range verification for D-Dimer and Anti-Xa. Reference range verification documentation for these two analytes was not found. The laboratory</p>

was unable to provide the missing documentation upon request. The laboratory director approved PV activities on 02/14/2024. 4. In an interview at 9:30 AM on 01/24/2025, the TS confirmed the above findings. 5. In an email received at 10:19 AM on 01/27/2025, the TS indicated 318 D-Dimer tests and 99 Anti-Xa tests were performed on patient samples between 02/16/24 and 01/24/25. .

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
. Based on observation, record review, and an interview with laboratory personnel, the laboratory failed to evaluate and document the relationship between two Chemistry testing methods at least twice annually in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 12:05 PM on 01/23/2024. 2. A Beckman DXC 700 was observed as present and available for Troponin testing during the tour. A Response Biomed RAMP instrument was listed as a back up method for Troponin testing until 06/01/2024 on the CCM Health Montevideo Test List provided by the laboratory. 3. A twice-annual process for comparison of test results obtained from multiple non-waived methods was found in the laboratory's Comparison Testing and Calibration Verification Review policy found within the Laboratory Quality Assessment Program procedure. 4. DXC 700 and RAMP test result comparison documentation from December 2023 was found in the Linearity Patient Comparison 2023 Calibration Verification binder. A second test result comparison between these two analyzers from 2023 was not found. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 1:53 PM on 01/24/2025, the TS confirmed the above finding. 6. In an email received at 10:19 AM on 01/27/2025, the TS indicated 5 patients were tested for Troponin on the back up Response Biomed RAMP instrument between June and December 2023. .