Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405562	12/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ccm Health	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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to follow the manufacturer's instructions to perform a study establishing the normal patient Prothrombin (PT) mean for each new lot ensuring the laboratory provided test results within stated performance specifications for Coagulation testing performed under the specialty of Hematology. Findings are as follows: 1. The laboratory performed Coagulation testing under the specialty of Hematology as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. The Instrumentation Laboratory ACL Top 300 Coagulation instrument was observed as present and available for use during the tour of the laboratory. 3. The package insert for the HemosIL RecombiPlasTin 2G (lot # N0320944) directed the laboratory to enter the International Sensitivity Index (ISI) value from the insert and establish the mean of the PT Normal Range with each new lot. 4. Documentation showing the new normal patient PT mean had been established with the most recent lot change was requested at 4:20 p.m. on 12/08/2022. The laboratory was unable to provide the documentation 5. In an interview at 8:30 a.m. on 12/09/22, TS1 confirmed the new lot had been put into use in August of 2022 and the laboratory had not performed a mean normal range study. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on document review, observation, and interview with laboratory personnel, the laboratory failed to ensure three of three vials of quality control (QC) material used for Hematology processing were not used after the expiration date had been exceeded in December 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. A Beckman Coulter DxH 520 Hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. A review of the QC File Reports for October 31, 2022, through December 7, 2022, found three of three QC levels were run when expired on 12/06 /2022 and 12/07/22. See below. QC material Lot number Expiration Date Abnormal low 352214111 12/05/2022 Normal 362214112 12/05/2022 Abnormal high 372214113 12/05/2022 4. At request, a list was generated, of patients tested on the Beckman Coulter DxH 520 during the period expired QC material was in use. One patient had hematology tests attempted on the analyzer on 12/06/2022, however the sample had clotting issues. The sample had to be redrawn and was tested on the alternative Hematology analyzer. 5. In an interview at 4:00 p.m. on 12/08/22, TS1 confirmed the above finding. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform, and document required daily maintenance for two of two Chemistry analyzers in 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. A Beckman Coulter ACCESS and Beckman Coulter DxC 700 chemistry analyzers were observed as present and available for use during the tour of the laboratory. 3. Manufacturer maintenance requirements for the Beckman Coulter ACCESS analyzer were established in the Beckman Coulter instructions for use ACCESS 2 manual located in the laboratory. The manufacturer requirements for daily startup maintenance on the Beckman Coulter DxC 700 analyzer were established on a flow chart posted near the instrument in the laboratory. The maintenance requirements were also found on the respective instrument maintenance logs. 4. Documentation of the daily maintenance performed on Beckman Coulter ACCESS analyzer was not found for 2 of 90 days reviewed on the January, February, and March 2022 instrument maintenance logs. February 4, 2022, and February 25, 2022, were not documented. 5. Documentation of the daily maintenance performed on Beckman Coulter DxC 700 analyzer was not found for 4 of 92 days reviewed on the July, August, and September 2021 instrument maintenance logs. July 13-16, 2021 were not documented. 6. In an interview at 2:30 p.m. on 12/08 /2022, TS1 confirmed the above finding. 7. The number of patients tested each day

	maintenance was missed on the Beckman Coulter ACCESS and Beckman Coulter DxC 700 are as follows: Date Number of patients tested February 4, 2022 22 February 25, 2022 25 July 13-16, 2021 123 .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 perform minimum quality control activities required for a Microbiology test system. Findings are as follows: 1. The laboratory performed C. Diff. testing under the subspecialty of Bacteriology as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. A Cepheid GeneXpert System was observed as present and available for use during the tour. The TS1 stated the Clostridium difficile (C. Diff.) assay was implemented on this system in September 2021. 3. The laboratory established an Individual Quality Control Plan (IQCP) to reduce the frequency of QC performance from 2 levels of control material each day of patient testing to once a month, when lab conditions change, when a new shipment is received, or when results are unexpected. The laboratory performed the IQCP on December 2, 2022, 15 months after the go live date of testing C. Diff. on the instrument. 4. The laboratory's records indicated QC was performed once a month since the go live date of September 2022 as follows: 09/01 /21 10/01/21 11/1/21 12/02/21 01/01/22 02/01/22 03/01/22 04/01/22 05/01/22 06/01 /22 07/01/22 08/01/22 09/01/22 10/01/22 11/01/22 12/01/22 5. Laboratory testing records indicated 13 patients received C. Diff. testing without daily QC since September 2021. See below. Date Patients tested 01/20/22 1 01/31/22 1 02/15/22 1 02 /24/22 1 03/22/22 1 04/07/22 1 04/18/22 1 05/18/22 1 07/26/22 1 09/13/22 1 10/27/22 1 11/17/22 2 6. In an interview at 8:55 a.m. on 12/09/22, TS1 confirmed the above finding. .
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 (QC) procedures performed to test Wright's stain for intended reactivity each day of use 4 of 30 days in April 2022. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed Technical

	Supervisor (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. The Quick-Dip QC log sheet for April 2022, was reviewed the day of survey. Testing personnel document the daily quality control check on this log. 6 of 30 days were missing documentation as follows: 04/02/22 04/03/22 04/24/22 04/26/22 04/28/22 04 /29/22 3. The Wright's Stain Policy (Quik Dip Stain Set) procedure found in the electronic PolicyStat database established QC requirement for the Wright's stain as follows: Quality Control, Daily, Hematology tech will check for stain quality at the beginning of their shift. Reagent appearance, and stained cell appearance will be noted. 4. In an interview at 3:42 p.m. on 12/09/22, TS1 confirmed the above finding. 5. At request, TS1 confirmed that 10 patients had a manual differential blood smear performed on the days the Wright stain QC was not documented. Data as follows: Date # of patients 04/03/22 1 04/26/22 3 04/28/22 1 04/29/22 5 .
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. (c) The laboratory must document all test result comparison activities. 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 Hematology instruments at least twice annually in 2021 and 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. The following Hematology instruments used for hematology testing were observed as present and available for use during the tour: Beckman Coulter DxH 600 - primary method Beckman Coulter DxH 520 - back up method 3. Laboratory records, evaluating the relationship between the two Hematology instruments were found documented as follows for 2021 and 2022: YEAR Date Performed 2021 03/25/21 2022 12/01/22 4. In an interview at 9:05 a.m. on 12/09/22, TS1 confirmed the above finding and that a Quality Assurance write-up was performed and signed by the Laboratory Director on 12/05/2022 when this was discovered. 5. The laboratory performs roughly 55,545 hematology tests annually as verified on the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, that was completed and signed by the Laboratory Director 12/08/2022 for the on-site recertification survey. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Supervisor failed to ensure 1 of 4 new testing personnel (TP) hired in 2021 and 2022, was evaluated for competency at least semiannually during the first year of patient

	specimen testing. Findings are as follows: 1. The laboratory performed testing in the specialties of Bacteriology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology as confirmed by Technical Supervisor 1 (TS1) during a tour of the laboratory at 10:45 a.m. on 12/08/22. 2. TP9 was hired and went through training and orientation in August 2021 as indicated in laboratory records. 3. The procedure, Laboratory Employee Performance and Competency Review, found in the software procedure system PolicyStat, indicated the assessment of each testing personnel's competency will occur at the 6-month interval. 4. A 6-month competency assessment was not found for TP9 during review of laboratory records. The laboratory was unable to provide the 6-month assessment upon request. 5. In an interview at 12:11 p.m. on 12 /08/22, TS1 confirmed the above findings. .