Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405562	12/13/2018
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to evaluate unacceptable proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/12/18 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received unacceptable PT results from API for the event and tests listed below. Event = 2017 - Chemistry / Core - 1st Event Sample = CH-03 Test = Cholesterol, Total Event = 2017 - Chemistry / Core - 1st Event Sample = CH-03 Test = Phosphorus Event = 2017 - Chemistry / Core - 1st Event Sample = CH-02 Test = Digoxin 4. An evaluation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide the evaluations upon request. 5. In an interview on 12/12/18 at 12:15 p.m., the GS confirmed the above findings. .
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by:

	. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of non-graded proficiency testing (PT) results. Findings are as follows: 1. The laboratory performed Chemistry and Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/12/18 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) as PT provider. 3. The laboratory received non-graded results from API due to no consensus for the events and tests listed below. Event = 2017 - Chemistry / Core - 3rd Event Sample ID = CM-11, CM-12, CM-13, CM-14, CM-15 Test = NT pro-BNP* Event = 2018 - Chemistry / Core - 2nd Event Sample ID = CM-06, CM-107, CM-08, CM-09, CM-10 Test = NT pro-BNP* Event = 2018 - Microbiology - 2nd Event Sample ID = UR-06 Test = Susceptibility (MIC) Testing: Piperacillin / Tazobactum Event = 2018 - Microbiology - 2nd Event Sample ID = RSP-10 Test = BioFire FilmArray RP / Influenza A 4. An evaluation of the non-graded PT results was not found during review of laboratory records. The laboratory was unable to provide the evaluations upon request. 5. In an interview on 12/12/18 at 12:15 p.m., the GS confirmed the above findings. * N-terminal-B-type natriuretic peptide .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to include accurate reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/12/18 at 10:05 a.m. 2. A Sysmex XT200i and a Sysmex KX21n Hematology Analyzer were observed as present and available for use during the tour of the laboratory. 3. The reference ranges in the Hematology Reference Ranges table, located in the Policy-Stat on-line procedure manual, did not reflect the reference range of values shown on a patient report (Female -68 yrs, Date performed = 10/20/2017) on the day of the survey. See below. Analyte: RDW* Table: 12.9 - 15.7 Patient Report: 12.0 - 15.7

	Analyte: Platelet Count Table: 130 - 450 Patient Report: 125 - 450 4. In an interview on 12/3/18 at 11:00 a.m., the GS confirmed the above findings. * Red Cell Distribution Width .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on an Immunoassay analyzer at least every 6 months. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 12/12/18 at 10:05 a.m. 2. A RAMP 200 Immunoassay analyzer was observed as present and available for use during the tour of the laboratory. 3. The laboratory exceeded the 6 month calibration verification interval for NT pro-BNP* testing performed on the Immunoassay analyzer on one occasion in the time period reviewed; January 2017 through December 2018. See below. Previous cal. December 2017 Date of survey 12/12/18 Time elapsed 12 Months 4. In an interview on 12/13/18 at 10:25 a. m., the GS confirmed the above finding. * N-terminal-B-type natriuretic peptide .