

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0696913	(X3) Date Survey Completed 02/20/2020
Name of Provider or Supplier Ccm Health - Clara City	Street Address, City, State 140 Nw 1st Ave, Clara City, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the reportable range values obtained during the performance verification on a new hematology analyzer were included in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:35 a.m. on 02/20/20. 2. A Beckman Coulter DxH 520 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities and began testing</p>

patient specimens using this analyzer in July 2019 as indicated in laboratory records. 3. The reportable ranges indicated in the DxH 520 Procedure, located in the Clara City Clinic Procedure Manual, for 8 of 12 analytes reviewed on date of survey did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated below. Analyte* PV Procedure WBC 0.00-98.73 0.00-100.0 HGB 0.00-21.73 0.20-22.00 MCV 68.4-99 68.0-98.0 RDW 11.7-18.4 11.7-19.0 NE% 40.3-84.69 0.00-100.0 LY% 9.19-47.21 0.00-100.0 MO% 2.23-18.46 0.00-100.0 EO% 0.66-11.8 0.00-100.0 4. In an interview at 12:20 p.m. on 02/20/20, the TC confirmed the above finding. The TC indicated the manufacturer's measuring range had been used as reportable range in the procedure. *Analytes WBC - White Blood Cells HGB - Hemoglobin MCV - Mean Corpuscular Volume RDW - Red Cell Distribution Width NE - Neutrophils LY - Lymphocytes MO - Monocytes EO - Eosinophils

D6052

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:
 . Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure competency assessment for 1 of 8 testing personnel included an evaluation of problem solving skills in 2019 for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:35 a.m. on 02/20/20. The non-waived tests included on the CCM Health - Clara City Clinic Laboratory Test Catalog In-House Testing table provided by the laboratory are listed below. Comprehensive Metabolic Profile Complete Blood Count Serum hCG Urine Microalbumin Microscopic examination - urine Microscopic Examination - skin Microscopic examination - vaginal wet preparation 2. The laboratory established problem solving skill evaluation requirements in the Competency Assessment procedure and the Lab Employee Performance and Competency Review form included an area for general assessment of problem solving skills. 3. The problem solving skill evaluation was not documented for Testing Personnel 2 in 2019 . 4. In an interview at 10:50 a.m on 02/20 /20, the TC confirmed the above finding.