

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1038677	(X3) Date Survey Completed 05/31/2019
Name of Provider or Supplier Stevens Community Medical Center-Starbuck Clinic	Street Address, City, State 501 Poler Street, Starbuck, 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
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between Hematology procedures and tables, and a patient test report. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 05/31/19. 2. A Sysmex XN-330 hematology analyzer was observed as present and available for use during the tour. The laboratory began testing patient specimens using this analyzer on 12/12/18 as confirmed in an interview with the LD at 3:15 p.m., on 05/31/19. 3. Reference intervals included in the Hematology Sysmex XN-330 standard operating procedure (SOP) and Starbuck Clinic In-House Test List Table for 14 of 14 analytes reviewed on date of survey were not consistent with those included on the patient test report reviewed, as indicated below. Patient: MRN #82505232 - adult male tested on 05/31/19. Analyte SOP / Table Report WBC Count * 4.23-9.07 4.5-11.0 RBC Count * 4.63-6.08 4.60-6.20 Hemoglobin 13.7-17.5 14.0-18.0 Hematocrit 40.1-51.0 42.0-52.0 MCV * 79.0-92.2 80.0-100.0 MCH * 25.7-32.2 26.0-33.0 MCHC * 32.3-36.5 31.0-36.0 Platelets 163-337 130-400 % Neutrophils 34.0-67.9 45.0-70.0 % Lymphocytes 21.8-53.1 28.0-55.0 % Monocytes 5.3-12.2 Not Given % Eosinophils 0.8-7.0 Not Given % Basophils 0.2-1.2 Not Given 4. In an interview at 3:15 p.m., on 05/31/19, the LD confirmed the reference interval discrepancies between the Sysmex XN-330 SOP and the patient test report. The LD stated that the reference intervals shown on the patient report were entered as part of a new Laboratory Information System (LIS), implemented on 10/1/18, and were taken from those used at a sister facility. *Note:</p>

WBC Count White Blood Cell Count RBC Count Red Blood Cell Count MCV Mean
Corpucular Volume MCH Mean Corpucular Hemoglobin MCHC Mean Corpucular
Hemoglobin Concentration .