Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0970975	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Stillwater Medical Group	700 Rivard St, Somerset, WI	

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	TEST REPORT CFR(s): 493.1291(d) 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. This STANDARD is not met as evidenced by: Item 1 Based on survey review of a patient's Chem 8 Panel test report and laboratory procedures and interview with the laboratory director and technical consultant, the reference ranges shown on the patient report was not the same as the approved reference ranges for four of nine chemistry analytes reviewed. Findings include: 1. Review of the reference range of the Chem 8 Panel test report from September 25, 2023, in the electronic medical record (EMR) for patient 1 (an adult male) showed the following expected ranges: Analyte/Reference range Sodium/136-145 milli moles /Liter (mmol/L) Potassium/3.5-5.1 mmol/L Chloride/98-109 mmol/L Carbon Dioxide-Total/22-31 mmol/L Anion Gap/7-16 mmol/L Ionized Calcium/1.18-1.32 mmol/L Glucose/70-180 milligrams/deciliter (mg/dL) Blood Urea Nitrogen/7-20 mg/dL Creatinine/0.7-1.2 mg/dL 2. Review of the "i-STAT-Chem8+" procedure showed the approved reference ranges for an adult male are: Analyte/Reference range Sodium /138-146 milli moles/Liter (mmol/L) Potassium/3.5-4.9 mmol/L Chloride/95-106 mmol/L Carbon Dioxide-Total/22-31 mmol/L Anion Gap/7-16 mmol/L Ionized Calcium/1.12-1.32 mmol/L Glucose/70-180 milligrams/deciliter (mg/dL) Blood Urea Nitrogen/7-20 mg/dL Creatinine/0.7-1.2 mg/dL Further review showed the sodium, potassium, chloride and ionized calcium reference ranges in the procedure did not match the patient's test report. 3. Interview with the laboratory director and technical consultant on January 9, 2024, at 1:55 PM confirmed the reference ranges in the EMR were not consistent with the approved reference ranges in the procedures. Item 2 Based on survey review of a patient's Complete Blood Count ((CBC) test report and laboratory procedures and interview with the laboratory director and technical

	consultant, the reference ranges shown on the patient report was not the same as the approved reference ranges for six of eight hematology analytes reviewed. Findings include: 1. Review of the reference range of the CBC test report from December 4, 2023, in the electronic medical record (EMR) for patient 1 (an adult male) showed the following expected ranges: Analyte/Reference range White Blood Cell (WBC)/3.5-10.5 x 10^9/Liter (L) Red Blood cell (RBC)/4.32-5.72 x 10^12/L Hemoglobin (HGB) /13.5-17.5 grams/deciliter (g/dL) Hematocrit (HCT)/38.8-50 percent (%) Mean corpuscular volume (MCV)/80.0-100.0 femtoliters (fL) Mean corpuscular hemoglobin (MCH)/27.6-33.3 picograms (pg) Mean corpuscular hemoglobin concentration (MCHC)/31.5-35.2 g/dL Platelets/150-450 x 10^9/L 2. Review of the "Hematology Normal Range" procedure showed the approved reference ranges for an adult male are: Analyte/Reference range WBC/4.0-11.0 x 10^9/Liter (L) RBC/4.5-5.9 x 10^12/L HGB/12.0-16.0 grams/deciliter (g/dL) HCT/36-46 percent (%) MCV/80.0-100.0 femtoliters (fL) MCH/26-34 picograms (pg) MCHC/32-36 g/dL Platelets/150-450 x 10^9/L Further review showed the WBC, RBC, HBG, HCT, MCH and MCHC reference ranges in the procedure did not match the patient's test report. 3. Interview with the laboratory director and technical consultant on January 9, 2024, at 1:55 PM confirmed the reference ranges in the EMR were not consistent with the approved reference ranges in the procedures.