Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2068222	04/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Marshfield Medical Center River Region	Suite A 4100 State Highway 66, Stevens Point, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 surveyor review of the laboratory's crossover studies performed for Prothrombin Time (PT) testing and International Normalized Ratio (INR) calculations with the Siemens CA-660 coagulation analyzer, observation of the CA-660 analyzer, and interview with a technical consultant (Staff A), the laboratory did not ensure the mean normal PT result and the international sensitivity index (ISI) used to calculate the INR were accurately entered into the analyzer for extended prothrombin time measurements for eight of the last eight months. Findings include: 1. Review of the laboratory's crossover studies for Innovin reagent lot 564671 performed in August 2025 showed the laboratory's calculated mean patient normal PT was 10.2 seconds and the ISI value from the manufacturer was1.05. 2. Observation of the CA-660 analyzer on April 29, 2026, at 2:10 PM revealed the current mean normal PT value in the analyzer for extended INR calculations was 10.1 seconds and the ISI was 1.09. Further observations confirmed the Innovin lot number currently in use for PT tests was lot 564671. 3. Interview with Staff A on April 29, 2026, at 2:10 PM confirmed staff did not update the mean normal PT or the ISI values for extended prothrombin time measurements in the CA-660 analyzer resulting in inaccurate INR calculations for tests performed using the extended PT measurement with the current Innovin lot 564671.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	(a)(1) 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 surveyor review of maintenance logs and records and interview with the technical consultant (Staff A), the laboratory failed to complete annual maintenance for the Beckman Coulter DX 520 hematology analyzer in one of two years. Findings include: 1. Review of the maintenance logs for the Beckman Coulter DX 520 hematology analyzer from 2025 and 2026 showed no evidence the laboratory performed the annual maintenance for the analyzer in 2025. 2. Review of the manufacturer's preventative maintenance records showed no evidence the manufacturer performed annual preventative maintenance in 2025 for the Beckman Coulter DX 520. 3. Interview with Staff A on April 29, 2026, at 1:00 PM confirmed the laboratory had no documentation of the performance of the annual maintenance for the Beckman Coulter DX 520 in 2025 as required by the manufacturer.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) (c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and This STANDARD is not met as evidenced by: Based on surveyor review of one of one test report from the AU480 analyzer and laboratory procedures and interview with a technical consultant (Staff A), the clinical consultant failed to ensure the reference range for the Anion Gap calculation on the test report was consistent with the reference range included in the test procedure. Findings include: 1. Review of a test report showed the reference range for an adult male for anion gap was 2 - 16 mmol/L (millimoles per liter). 2. Review of the "Bicarbonate AU Series" procedure showed the anion gap reference range for an adult male was 3 - 16 mmol/L. 3. Interview with Staff A on April 29, 2026, at 2:30 PM revealed the laboratory's reference range for the anion gap calculation for an adult male on the test report was different from the reference range approved in the procedure.