Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0887068	08/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mainstreet Clinic	1001 W Main St, Ashland, 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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with Testing Personnel (Staff A), the laboratory did not perform i-STAT thermal probe checks every six months in two of the last two years. Findings include: 1. Review of laboratory records showed no evidence staff had performed thermal probe checks on the i-STAT analyzer. 2. Review of the 'i-STAT Procedure' showed the procedure required performance of the thermal probe checks every six months. 3. Interview with Staff A on August 13, 2024, at 2:30 PM confirmed thermal probe checks had not been performed on the i-STAT analyzer.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on surveyor review of laboratory procedures and records and interview with Testing Personnel (Staff A), the Laboratory Director did not ensure one of one Individualized Quality Control Plan (IQCP) was reviewed annually since August 9, 2022. Findings include: 1. Review of the laboratory's quality management plan showed the laboratory required annual review of the IQCP with the other procedures. 2. Review of the IQCP showed the Laboratory Director reviewed the plan on August 9, 2022. 3. Interview with Staff A on August 13, 2024, at 2:40 PM confirmed the Laboratory Director had not reviewed the IQCP since August 9, 2022, and confirmed the director had not established and maintained a quality assessment program for review of the IQCP to assure quality of laboratory services.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on surveyor review of competence evaluation records and interview with Testing Personnel (Staff A), the technical consultant did not evaluate and document the annual evaluation of Staff A one of the last two years. Findings include: 1. Review of competence evaluation records showed no evidence of evaluation of Staff A in 2023. 2. Interview with Staff A on August 13, 2024, at 1:30 PM confirmed the technical consultant did not complete a competence evaluation for Staff A in 2023 for the testing performed in the laboratory.