Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396915	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Spooner Health System	1280 Chandler Dr, Spooner, 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 observation of supplies in the laboratory and interview with the Technical Consultant (Staff A), the laboratory did not follow the manufacturer's instructions for the Activate Bleach Dilution System used to control cross-contamination of testing performed with the BIOFIRE FILMARRAY TORCH system. Findings include: 1. Observation in the microbiology laboratory on February 24, 2026, at 8:00 AM revealed an Activate Bleach Dilution System including a spray head, a water bottle and a bleach bottle. The original expiration date (11/25/2025) was crossed off on the bleach bottle and the bottle was labeled with a new expiration date, 7-8-26. The manufacturer's instructions on the bottle included the following statement, "Non-refillable container. Do not re-use or refill this container." 2. Interview with Staff A on February 24, 2026, at 8:00 AM revealed the laboratory used the Activate Bleach Dilution System to control cross-contamination and that the laboratory continued using the dilution system after staff refilled the bleach bottle. Further interview confirmed the laboratory did not follow the manufacturer's instructions.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records for the Vitek 2 analyzer and interview with the Technical Supervisor (Staff A), the laboratory did not have an ongoing mechanism to identify recurring quality control failures for antimicrobial susceptibility testing (AST). Records from four of five reviewed months showed the analyzer identified a positive Cefoxitin Screen for gram positive (GP) organisms when the expected result was negative. Findings include: 1. Review of QC records for AST using the AST-GP67 card showed positive Cefoxitin Screen results in June 2024, June 2025, October 2025 and November 2025. Results from January 2026 were as expected. Review of the 'Corrective Action For Vitek QC' logs from June 20, 2024, June 26, 2025, October 23 and 30, 2025, and November 20, 2025, showed testing personnel identified potential suspension problems and reset the QC. The forms showed, "Repeated QC is within acceptable range, no further corrective action needed". 2. Interview with Staff A on February 24, 2026, at 9:00 AM confirmed the laboratory did not have a mechanism to monitor and assess recurring quality control failures for AST testing to determine whether the laboratory needed to take additional corrective actions.