Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396915	01/18/2024
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of calibration verification records, quality control (QC) records and interview with the technical consultant, the laboratory did not perform calibration verification every six months for two of two analytes on the Biomerieux Vidas 3 chemistry analyzer in 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Vidas 3 analyzer November 11, 2021, and November 4, 2022. Further review showed no evidence of

	additional calibration verification performed for D-dimer and procalcitonin on the analyzer in 2022 when calibration verification was due on May 11, 2022. 2. Review of the "DAILY QC LOG" for the Vidas 3 showed one hundred seventeen patient testing days for D-dimer and one hundred twenty-seven patient testing days for procalcitonin between May 11, 2022, and November 4, 2022. 3. Interview with the technical consultant on January 17, 2024, at 3:34 PM confirmed the laboratory performed the laboratory did not perform calibration verification every six months on the Biomerieux Vidas 3 chemistry analyzer in 2022.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review quality control (QC) records, U.S. Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) classification database and Individualized Quality Control Plans (IQCP) and interview with the technical consultant and testing personnel, staff A, the laboratory did not perform QC each eight hours of patient testing on the Vidas 3 D-dimer test for forty-four of one hundred fifty patient tests between October 1, 2024 and January 17, 2024, and had not developed an IQCP. Findings include: 1. Interview with staff A on January 17, 2024, at 2:20 PM stated QC was performed on the Vidas 3 D-dimer test once per 24 hours of patient testing. 2. Review of QC records for D-dimer testing on the Vidas 3 chemistry analyzer showed QC was run one time every 24 hours of patient testing from October 1, 2023 and January 17, 2024. 3. Review of the FDA CLIA classification database showed D-dimer testing on the Vidas 3 chemistry analyzer is classified as a hematology test. 4. Review of the laboratory's IQCPs showed no evidence of an IQCP for the Vidas 3 D-dimer test. 5. Interview with the technical consultant on January 17, 2024, at 2:30 AM confirmed the laboratory did not perform QC each eight hours of patient testing on the Vidas 3 D-dimer test and had not developed an IQCP.