Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396915	01/26/2022
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) reports and Wisconsin State Laboratory of Hygiene (WSLH) PT records, and interview with the administrative laboratory director, the laboratory failed to successfully participate in four of six events for the Compatibility Testing subspecialty in the Immunohematology specialty in 2021 and 2020. Findings include: 1. Review of PT records in the federal CASPER reporting system as of January 20, 2022 showed the laboratory had unsatisfactory performance for compatibility testing on events one and two in 2020 and events two and three in 2021. A score of 100% is required for satisfactory performance for compatibility

	testing. Event 2020-1, score 80% Event 2020-2, score 80% Event 2021-2, score 0% Event 2021-3, score 80% 2. Surveyor review of the WSLH PT evaluation report confirmed the unsatisfactory scores for compatibility testing for two consecutive PT events in 2021 which results in unsuccessful participation in PT for compatibility testing. 3. Surveyor review of the federal CASPER reporting system shows this is a subsequent unsuccessful PT performance and a repeat deficiency which was cited September 30, 2020. See D 2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) reports and Wisconsin State Laboratory of Hygiene (WSLH) PT records, and interview with the administrative laboratory director, the laboratory failed to successfully participate in PT for the Compatibility Testing subspecialty in the Immunohematology specialty in four of six events in 2020 and 2021. Findings include: 1. Review of PT records in the federal CASPER reporting system as of January 20, 2022 shows the laboratory had unsatisfactory performance for compatibility testing on events one and two in 2020 and events two and three in 2021. A score of 100% is required for satisfactory performance for compatibility testing. Event 2020-1, score 80% Event 2020-2, score 80% Event 2021-2, score 0% Event 2021-3, score 80% 2. Surveyor review of the WSLH PT evaluation reports confirmed the unsatisfactory scores for compatibility testing for two consecutive PT events in 2021 which results in unsuccessful participation in PT for compatibility testing. 3. Surveyor review of the federal CASPER reporting system shows this is a subsequent unsuccessful PT performance and a repeat deficiency which was cited September 30, 2020. 4. Interview with the administrative laboratory director (staff A) on January 25, 2022 at 8:45 AM confirmed the laboratory failed to successfully participate in PT for the Compatibility Testing subspecialty in the Immunohematology specialty in two events in 2021 and two events in 2020.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the new procedure for Erythrocyte Sedimentation Rate (ESR or Sedrate) using the Alcor Scientific miniiSED analyzer did not include the laboratory's reference intervals (normal values). Findings include: 1. Review of the 'miniiSED-Sedrate Rate' Procedure (Policy #: 010H-128) showed the expected results section of the procedure identified the reportable range for the test system. EXPECTED RESULTS Reportable range: 1-130 mm/hr (millimeters per hour) Further review of the procedure showed no identification of the laboratory's reference intervals for this procedure. 2. Interview with the technical consultant on January 25, 2022 at 3:50 PM confirmed the procedure did not include the reference intervals for test results
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and test records and interview with the technical consultant, the procedure for Erythrocyte Sedimentation Rate (ESR or Sedrate) using the Alcor Scientific miniiSED was not approved by the laboratory director before use for patient testing. Findings include: 1. Review of the electronic record of the 'miniiSED-Sedrate Rate' Procedure (Policy #: 010H-128) showed the director approved, signed and dated the procedure on September 14, 2020. No record of approval prior to September 14, 2020 was available. 2. Review of testing records showed the first day of patient testing with the miniiSED test system was August 21, 2020. 3. Interview with the technical consultant on January 25, 2022 at 3:55 PM confirmed the laboratory director had not signed and dated the procedure before the laboratory used the Alcor Scientific miniiSED analyzer for patient testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory freezer number 2, review of temperature records, and interview with the technical consultant, the laboratory did not define an

	acceptable temperature range that was consistent with the manufacturer's instructions for the BioFire controls stored in the freezer. Findings include: 1. Observation of the Helmer freezer in the laboratory (Freezer 2) on January 26, 2022 at 12:55 PM showed the temperature in the freezer was -30.5 degrees Celsius (C). Observation of the BioFire control material stored in the freezer showed the manufacturer required storage at -15 to -25 C. 2. Review of temperature logs from December 2021 showed the defined acceptable temperature range for Freezer 2 was less than -20 C. Thirty of thirty-one days showed recorded temperatures were less than -25 C. 3. Interview with the technical consultant on January 26, 2022 at 12:55 PM confirmed the laboratory's acceptable range for the freezer was not consistent with the manufacturer's acceptable range for storage of the BioFire control material.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's verification studies for the Alcor Scientific miniiSED analyzer and interview with the technical consultant, the laboratory did not document verification that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population. Findings include: 1. Review of the laboratory's verification studies for the Alcor Scientific miniiSED analyzer showed no evaluation of the manufacturer's reference intervals. 2. Interview with the technical consultant on January 25, 2022 at 3:55 PM confirmed the verification studies did not address the reference intervals for the test system. This is a repeat deficiency previously cited on February 6, 2020.