Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396915	02/06/2020
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency test (PT) records and interview with the general supervisor, the laboratory director or a qualified designee did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for six of six immunohematology events in 2018 and 2019. Findings include: 1. Review of American Proficiency Institute (API) immunohematology PT records showed the laboratory director, who is the immunohematology technical supervisor, did not sign six of six attestation statements in 2018 and 2019. 2. Interview with the general supervisor on February 5, 2020 at 11:22 AM confirmed the laboratory director or a qualified designee did not sign immunohematology events in 2018 and 2019.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from four events in 2018 and 2019, laboratory procedures, and interview with the general supervisor, testing personnel repeated the antibody screen for six of twelve samples with negative

	antibody screen results while patient samples with negative antibody screen results were not repeated. Findings include: 1. Review of immunohematology PT records for all events in 2018 and event one of 2019 revealed twelve samples had negative antibody screens. Further review showed the antibody screen on the following six samples was repeated by a second testing person: a. 2018-1: Ser-02 and Ser-05 b. 2018-2: Ser-09 c. 2018-3: Ser-14 d. 2019-1: Ser-01 and Ser-04 The testing records do not indicate a reason for the repeated analysis. 2. Review of the "MTS Antibody Screen" procedure under "Interpretation of Results" revealed testing personnel do not repeat negative antibody screen testing. 3. Interview with the general supervisor on February 5, 2020 at 11:35 AM confirmed testing personnel repeated negative antibody screens for proficiency testing when patient negative antibody screens are only tested once.
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: Item 1: Based on surveyor review of performance verification records for the STAT Site M beta-hydroxybutyrate analyzer and interview with the general supervisor, the laboratory did not verify the precision or reference intervals for this test system prior to performing patient testing. Findings include: 1. Review of performance verification records for the STAT Site M showed no evidence the precision and reference intervals were evaluated prior to testing patient samples. 2. Interview with the general supervisor on February 5, 2020 at 3:28 PM confirmed the laboratory did not evaluate precision and reference intervals prior to testing patient samples. Item 2 Based on surveyor review of performance verification records for the STAT Site M beta-hydroxybutyrate analyzer and interview with the general supervisor, the laboratory did not document review and evaluation of the verification data prior to performing patient testing. Findings include: 1. Review of the performance verification records for the STAT Site M showed no evidence the laboratory reviewed and evaluated the data prior to testing patient samples. 2. Interview with the general supervisor on February 5, 2020 at 3:28 PM confirmed the laboratory did not have documentation the performance verification was reviewed and evaluated prior to testing patient samples.