Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393990	(X3) Date Survey Completed 01/16/2020
Name of Provider or Supplier St Clare Hospital And Health Services	**Street Address, City, State** 707 14th St, Baraboo, 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
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the administrative laboratory director, the laboratory director did not delegate, in writing, the general supervisor responsibilities for the immunohematology area to the individual performing the duties after October 2019. Findings include: 1. Review of immunohematology maintenance, quality control, and quality management records showed testing personnel (staff A) performed the duties of the immunohematology general supervisor in November and December 2019. 2. Interview with the administrative laboratory director (staff B) on January 16, 2020 at 2:00 PM confirmed staff A performed the duties of the immunohematology general supervisor after the previous immunohematology lead left the laboratory in October 2019. Further interview confirmed the laboratory director had not delegated the general supervisor responsibilities to staff A in writing.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on surveyor review of competency evaluation records and interview with the administrative laboratory director, the laboratory did not have annual immunohematology blood bank competency documentation for one of four testing personnel in 2019. Findings include: 1. Review of records for testing personnel staff C showed the laboratory did not have records of annual competency evaluation for 2019. 2. Interview with the administrative laboratory director (staff B) on January 16, 2020 at 2:00 PM confirmed the laboratory did not have records available to show the laboratory completed immunohematology competency evaluation of staff C in 2019.