Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661966	(X3) Date Survey Completed 11/15/2018
Name of Provider or Supplier Memorial Hospital Of Lafayette County	**Street Address, City, State** 800 Clay St, Darlington, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory blood bank records and interview with the general supervisor, the coombs check cells used for testing on October 21, 2018 were expired. 1. Review of the blood bank testing log shows Ortho coombs check cells lot K526 with an expiration date of October 16, 2018, were used on October 21, 2018 for quality control and proficiency testing. 2. Interview with the general supervisor on November 15, 2018 at 1:00 PM confirms that expired coombs check cells were used past the expiration date as were available for patient testing.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 laboratory record review and interview with the technical consultant, the laboratory director has not delegated in writing responsibilities to the technical consultant to perform specific delegated duties in which the technical consultant has been performing. Findings include: 1. Review of laboratory technical competency assessments, quality control, and new method evaluation records shows the technical consultant has reviewed and approved these records. 2. Review of laboratory records shows no written delegation by the lab director to the technical consultant to perform these responsibilities. 3. Interview with the lab director and technical consultant on November 14, 2018 at 10:30 AM confirms the lab director has not delegated in writing the duties and responsibilities of the technical consultant.