Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 52D0665972	**(X3) Date Survey Completed** 01/05/2018
Name of Provider or Supplier Spring Green Medical Center	**Street Address, City, State** 150 Jefferson St, Spring Green, 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**
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on surveyor review of validation studies performed on the Abbott Emerald hematology analyzer and interview with the Technical Consultant, the Laboratory Director did not evaluate the testing system to ensure provision of quality laboratory services prior to use for patient testing. Findings include: 1. Review of validation studies for the Abbott Emerald hematology analyzer show the Laboratory Director reviewed and approved the validation studies on February 2, 2017. The analyzer started patient testing on January 9, 2017. 2. Interview with the laboratory Technical Consultant on January 5, 2018 at 12:00 PM confirmed the Laboratory Director did not review and approve the results of the validation studies prior to the start of patient testing on the analyzer to ensure the new hematology analyzer provided quality laboratory services.