Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0039725	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Prairie Ridge Health, Inc	1515 Park Ave, Columbus, 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
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 the laboratory procedures, records received by the Wisconsin state agency, and interview with the general supervisor, the laboratory procedures have not been approved, signed, and dated by the current laboratory director since February 2016 when the current lab director assumed the role. Findings include: 1. Review of the laboratory procedures shows no evidence of review and approval of all of the procedures by the current laboratory director. 2. Review of Wisconsin state agency records show the laboratory changed the director to the current director effective February 1, 2016. 3. Interview with the general supervisor on May 14, 2019 at 10:30 AM confirms all of the procedures in use in the laboratory have not been approved, signed and dated by the current director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of test equipment, and interview with the general supervisor, the laboratory did not verify the geometric

	mean was accurately entered into the coagulation analyzer for the current lot of RecombiPlasTin reagent that was in use. Findings include: 1. Review of laboratory records showed the laboratory started using the current lot number of RecombiPlasTin 2G reagent October 19, 2018. Further review shows the geometric mean for this lot number was 11.0 seconds. 2. Observation of the ACL Elite coagulation analyzer on May 14, 2019 at 09:15 AM shows the geometric mean in the analyzer was set at 11.3 seconds. The geometric mean is used with the RecombiPlasTin 2G International Sensitivity Index (ISI) to calculate the patient International Normalized Ratio (INR). Patient INR results are reported in the laboratory. 3. Interview with the general supervisor on May 14, 2019 at 09:15 AM confirmed the geometric mean entered into the coagulation analyzer and used to calculate patient INR results was not correct.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control records and interview with the general supervisor, the laboratory does not use an elevated serum bilirubin control for monitoring the abnormal high range of neonatal bilirubin testing. Findings include: 1. Review of chemistry quality control (QC) records for the bilirubin test show that two levels of QC are performed each day of testing, and that an elevated bilirubin control for monitoring the abnormal high range of neonatal bilirubin's is not performed when neonatal bilirubin tests are performed. 2. Interview with the general supervisor on May 14, 2019 at 2:45 PM confirmed that the laboratory does not use an elevated serum bilirubin control for monitoring the abnormal high range of neonatal bilirubin testing.