Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0680567	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Aurora Health Center - West Bend, Valley Ave	**Street Address, City, State** 205 Valley Ave, West Bend, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of the coagulation analyzer, and interview with the technical consultant, the laboratory's quality assurance process for evaluating the accuracy of the INR (International Normalized Ratio) calculation did not identify an incorrect mean patient Protime (PT) value used in the calculation. Findings include: 1. Review of the ACL 2017 Reagent/QC (Quality Control) Roll-Over Checklist for this laboratory showed the geometric mean of normal patient values for lot #549704 equaled 9.9 seconds. Review of the Mean Normal Value for the Calculation of PT/INR worksheet showed the value of the geometric mean is 9.845 for Innovin lot #549704. 2. Observation of the coagulation analyzer at 11:30 AM on February 22, 2018 showed a mean normal patient value of 9.9 seconds in use for the INR calculation. Observation of coagulation reagents showed lot # 549704 was in use. 3. Interview with the technical consultant on February 22, 2018 at 11:30 AM confirmed the calculated geometric mean for the normal patient protime result was incorrectly entered on the Roll-Over Checklist and on the analyzer as 9.9 instead of 9.8. Further interview confirmed the laboratory's quality assessment procedures did not identify the error.