Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2077860	02/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Health Center - West Bend, Gateway Ct	1100 Gateway Ct, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, patient test logs, quality control records, and interview with the technical consultant, the laboratory did not perform quality control for serum human chorionic gonadotropin (HCG) on two days of patient testing in September 2018 and December 2019. Findings include: 1. Review of the "HCG Serum-Urine QuickVue +" procedure showed external quality controls are tested and recorded each day patient testing is performed. 2. Review of serum HCG patient test logs revealed the laboratory performed testing on Patient 1 on September 7, 2018 and Patient 2 on December 6, 2019. 3. Review of quality control records from September 2018 and December 2019 showed no documentation of quality control for September 7, 2018 and December 6, 2019. 4. Interview with the technical consultant on February 12, 2020 at 10:28 AM confirmed the laboratory did not document quality control on the serum HCG test on days of patient testing on September 7, 2018 and December 6, 2019.