

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0901655	(X3) Date Survey Completed 12/17/2018
Name of Provider or Supplier Aurora Health Center-Waukesha	Street Address, City, State W231 N1440 Corporate Court, Waukesha, 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
D5461	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g)</p> <p>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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and interview with the technical consultant, the laboratory did not test quality control material before testing patient samples with a new lot of troponin reagents on the i-STAT analyzer. Findings include: 1. Review of the "WAUK i-STAT cTnl Quality Control Log" showed troponin cartridge lot number M1812713 was first tested with control material on July 8, 2018. The log showed July 1, 2018 as the 'date in use' for this cartridge lot. 2. Interview with the technical consultant, staff A, on December 17, 2018 at 10:30 AM confirmed troponin patient testing was performed prior to testing control materials on the i-STAT analyzer after a change to a new reagent lot number.</p>