Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1021288	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
A2cl-Aurora Health Center Manitowoc County	5300 Memorial Drive-Attn Lab Supervisor, Two Rivers, 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 quality control records, patient test logs, Individualized Quality Control Plan (IQCP) and interview with the general supervisor, the laboratory did not perform quality control prior to reporting patient results on serum human chorionic gonadotropin (HCG) testing with lot# 704702. Findings include: 1. Review of quality control records from September and October 2019 showed the laboratory performed serum HCG quality control on Lot# 704702 on September 14, 2019. 2. Review of serum HCG patient test logs revealed the laboratory performed testing on Patient 1 using Lot# 704702 on October 22, 2019. 3. Review of serum HCG IQCP showed the laboratory required quality control every 30 days and/or with each new shipment/lot. 4. Interview with the general supervisor on January 14, 2020 at 1:29 PM confirmed the laboratory did not perform quality control on the serum HCG test prior to reporting patient results using Lot# 704702 as indicated in their IQCP quality control plan.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d)

	(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Siemens CA-660 coagulation analyzer printouts and interview with the general supervisor, the laboratory did not perform quality control (QC) each eight hours of operation on the coagulation analyzer on two days in December 2019 and January 2020. Findings include: 1. Review of Siemens CA-660 printout revealed: On December 16, 2019, QC performed at 8:33 AM, Patient 2 testing performed at 5:01 PM. No additional QC performed between the two times. On January 6, 2020, QC performed at 8:51 AM, Patient 3 testing performed at 5:27 PM. No additional QC performed between the two times. 2. Interview with the general supervisor on January 14, 2020 at 1:07 PM confirmed the laboratory did not perform quality control each eight hours of operation prior to patient testing on the Siemens CA-660 coagulation analyzer.