Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2150696	05/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Health Center- Manitowoc	3509 Dewey St, Manitowoc, 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
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory administrative director, the procedure for serum hCG (human chorionic gonadotropin) did not include the date of initial use for this laboratory. Findings include: 1. Review of the serum hCG procedure shows the laboratory director approved the procedure in 2013. Further review shows no initiation date for this laboratory. 2. Interview with the laboratory administrative director, staff A, on May 7, 2019 at 12:00 PM confirmed the procedure did not include an initiation date for this laboratory. Further interview revealed the laboratory started patient testing on August 9, 2018.
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 the Individualized Quality Control Plan (IQCP) for serum human chorionic gonadotropin (hCG), patient test logs, and monthly quality control logs, and interview with the laboratory administrative director, the laboratory did not test external controls as required in their IQCP with two of two patient samples tested between January 18, and February 3, 2019. Findings include: 1. The quality control plan of the laboratory's IQCP for serum hCG testing requires testing two internal and two external controls daily with each patient specimen. 2. Review of the "QuickVue+ hCG Patient Test Log" from January 18, 2019 through February 3, 2019 shows serum hCG testing was performed on January 18 and 31, 2019. 3. Review of the "HCG Quick Vue Monthly Quality Control Log" showed no record of external control testing on January 18 or 31, 2019. 4. Interview with the laboratory administrative director, staff A, on May 7, 2019 at 10:30 AM confirmed testing personnel did not perform external controls with patient testing as required in the serum hCG IQCP tests.