Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382810	05/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ellsworth Municipal Hospital	920 South Oak Street, Iowa Falls, IA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 05/24/2018, the laboratory failed to verify the accuracy for direct antiglobulin testing (DAT) twice annually for four out of four time periods in 2016 and 2017. At the time of the survey, laboratory personnel identifier #1 confirmed that the laboratory had not verified the accuracy for DAT testing in 2016 and 2017.
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 lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1

	(refer to the Laboratory Personnel Report) at approximately 12:20 pm on 05/24/2018, the laboratory failed to perform a positive and negative control each day of patient testing for the Immunocard STAT Helicobacter pylori (H. pylori) test system. The findings include: 1. The laboratory performed controls with each new lot of tests for the H. pylori test system. 4. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 5. At the time of the survey, the laboratory did not have an IQCP for the Immunocard STAT H. pylori test system.