Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445317	06/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ellett Memorial Hospital	610 N Ohio Ave, Ne Hall, Appleton City, MO	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's inserts and interview with testing personnel #1, the laboratory failed to monitor and document the humidity of the laboratory for proper operation of the Sysmex XS 1000i. 1. Review of the manufacturer's product insert for performance specifications revealed to operate the analyzer in relative humidity of 30-85 percent. 2. Review of the room temperature documentation logs showed the laboratory failed to document humidity. 3. Interview with the testing personnel #1 on June 18, 2018 at 2:00 PM confirmed the laboratory failed to document the room humidity in the laboratory where the Sysmex XS 1000i hematology analyzer was in operation.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of quality control (QC) procedures and interview with the testing personnel #1, the laboratory failed to perform QC each day of patient testing for Medtox Scan drugs of abuse. Findings: 1. Review of QC procedure for Medtox Scan Drugs of abuse showed the laboratory performed a positive and negative external control weekly. 2. Interview with testing personnel #1 on June 18, 2018 at 1:00 PM confirmed the laboratory did not test a positive and negative control each day of testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of iStat blood gas controls, procedures and interview with testing personnel #1 the laboratory failed to follow quality control (QC) procedure before reporting patient's test results. Findings: 1. Review of quality control procedure states 2 levels of liquid QC every 24 hours of patient testing. 2. Review of patient reports shows patient results were reported out on 2/25/18 and pH and pCO2 for level 1 and level 3 were not in acceptable range: pH level 1 control was 7.595 acceptable range 7.005-7.105 pH level 3 control was 7.888 acceptable range 7.634-7.734 pCO2 level 1 control was 8.9 acceptable range 7.82-8.82 pCO2 level 3 control was 12.9 acceptable range 16-21.6 3. Interview with testing personnel #1 on June 18, 2018 at 1:00 PM confirmed the laboratory did not follow procedure and run acceptable quality control before each patient.