Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0521434	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Weiser Memorial Hospital	645 E 5th St, Weiser, ID	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to document calibration verification procedures for electrolytes performed on the Siemens Dimension chemistry analyzer at least once every 6 months or as required by the manufacturer since the last survey on February 2, 2017. Findings: 1. A record review of calibration reports revealed the laboratory failed to perform calibration verification on electrolytes since the last survey. 2. An interview

	on November 2, 2018 at 1:15 PM, with the laboratory manager, confirmed the laboratory failed to perform and document calibration verification activities on the electrolytes.
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 a record review and an interview with the laboratory manager, the laboratory failed to perform control procedures at least once each day of patient testing on the MedTox urine drug screen device and the i-Stat Blood Gas device since the last survey on February 2, 2017. Findings: 1. A review of the quality control records for the MedTox and i-Stat devices revealed the laboratory failed to perform quality control at least once each day of patient testing since the last survey. 2. An interview on November 2, 2018 at 1:25 PM with the laboratory manager, confirmed the laboratory failed to perform quality control each day of patient testing and did not write an Individualized Quality Control Plan for the test systems.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a record review of personnel documents and an interview with the laboratory manager, the technical supervisor who is the laboratory manager failed to include assessment of test performance through blind testing or proficiency testing in the competency evaluations for testing personnel since the last survey on February 2, 2017. Findings: 1. A review of the personnel competency evaluations for 2017 and 2018 revealed the assessments failed to include the evaluations of test performances through blind testing or proficiency testing for 10 out of 10 testing personnel. 2. An interview on November 2, 2018 at 8:45 AM, with the laboratory manager, confirmed the competency assessment forms failed to include the evaluation of test performance through blind testing or proficiency testing.