Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441828	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Center	611 West Main, Fredericktown, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the Hematology procedure manual and interview with the general supervisor, the laboratory failed to include reference intervals(normal values) for manual white blood cell(WBC) differentials. Findings: 1. Review of the procedure manual revealed a lack of normal values for WBC manual differentials. 2. Interview with the general supervisor on February 27, 2018 at 11:30 AM confirmed the laboratory failed to include normal values for WBC manual differentials.
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 review of quality control procedures for blood gases and troponin and interview with the general supervisor the laboratory failed to document control procedures completely. Findings: 1. Review of control procedures for blood gases and troponin showed laboratory developed an Individualized quality control plan (IQCP) for blood gases and troponin. An IQCP is a quality control procedure which includes risk assessment, quality control plan and quality assessment. 2. Review of the IQCP showed a lack of supporting data and historical data for the risk assessment for blood gases and troponin. 4. Interview with the general supervisor on February 27, 2018 at 12:05 PM confirmed the laboratory failed to complete the risk assessment for the IQCP.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control(QC) documents for bacteriology and interview with the general supervisor, the laboratory failed to check each batch of blood culture media for its ability to support growth. Findings: 1. Review of QC logs showed the laboratory failed to check each batch of blood culture media for its ability to support growth. 2. Interview with the general supervisor on February 27, 2018 at 11:00 AM confirmed the laboratory failed to check each batch of blood culture media for its ability to support growth.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of 2017 chemistry comparison records for Troponin and Chem 8 performed on the primary analyzer and secondary analyzer and interview with the general supervisor on February 27, 2018 at 11:00 AM, the laboratory failed to perform and evaluate the relationship between the Abbott i-STAT and Abbott Architect twice a year. Findings: 1. Review of comparison records for Troponin and Chem 8 on the primary analyzer, Abbott Architect and the secondary analyzer, Abbott i-STAT, revealed a lack of documentation twice yearly for 2017. 2. Interview with the general supervisor on February 27, 2018 at 11:00 AM confirmed the laboratory failed to perform and document twice a year for 2017 the comparison of the Abbott i-STAT and Abbott Architect for Troponin and Chem 8.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competencies and interview with the general supervisor the technical supervisor failed to document and approve competency in 2016 for one of nine testing personnel. Findings: 1. Review of competencies showed testing personnel #1 did not have a competency in 2016 documented and approved by the technical supervisor. 2. Interview with the general supervisor on February 27, 2018 confirmed the technical supervisor failed to document and approve competency for one testing personnel in 2016.