Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046175	01/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bates County Memorial Hospital	615 W Nursery St, Butler, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with testing personnel #1 on January 3, 2018 at 12:00 PM confirmed, the laboratory failed to have a written policy available for specimen processing, specimen acceptability and rejection for chemistry and coagulation testing.
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 laboratory procedure manuals and interview with testing personnel #1 on January 3, 2018 at 12:00 PM confirmed, the manuals failed to include the speed and time for centrifuging /processing chemistry and coagulation patient specimens prior to testing.
D5501	BACTERIOLOGY CFR(s): 493.1261(a)(1) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(1) Each day of use for beta-lactamase methods other than Cefinase(trademark). This STANDARD is not met as evidenced by: Based on review of bacteriology quality control (QC) procedures, QC records for 2017 and to date January 3, 2018, and interview the laboratory failed to check positive and negative reactivity each day of use for non-Cefinase beta-lactamase methods. Findings: 1. Review of bacteriology QC procedures revealed the laboratory performs QC on a non-Cefinase beta-lactamase method with each new lot number, new shipment or every six months. QC records revealed the laboratory last checked positive and negative reactivity on August 18, 2017. 2. Interview with testing personnel #1 revealed the laboratory performed approximately 10 patient beta-lactamase tests since August 18, 2017. Interview with testing personnel #1 on January 3, 2018 at 11:00 AM confirmed the laboratory failed to check the beta-lactamase method in use for positive and negative reactivity each day of patient testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control procedures (QC) and interview with general supervisor, the director failed to establish written criteria /procedures for acceptability of quantitative QC test results. Findings: 1. Review of QC procedures revealed the laboratory did not have a written procedure that defined acceptable statistical parameters / standard deviations for quantitative QC test results (QC runs). 2. Interview with the general supervisor on January 3, 2018 at 1:00 PM confirmed, the laboratory did not have a written procedure, approved by the director, for acceptability of quantitative QC test results.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of competencies and interview with the technical supervisor, the technical supervisor failed to complete and document a semiannual competency for one of twelve testing personnel. Findings: 1. Review of competencies showed testing personnel #6 did not have a semiannual competency during the first year of laboratory testing. 2. Interview with the technical supervisor on January 3, 2017 at 12:15 PM confirmed testing personnel #6 did not have a semiannual competency completed and documented during the first year of laboratory testing.