Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046175	01/07/2020
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, quality control (QC) / patient records for 2019 and to date January 7, 2020 and interview with technical supervisor #1, the laboratory failed to follow the procedure manual for recording reagent lot number (#) information in the blood bank log book. Findings: 1. The blood bank procedure manual states," Reagent lot # and expiration date should be recorded in the blood bank log book along with the results." 2. The laboratory did not document /record reagent lot # for QC and patient use in the blood bank log book from May 2019 through January 7, 2020. 3. Interview with technical supervisor #1 on January 7, 2020 at 11:50 AM confirmed the laboratory failed to document reagent lot # in the blood bank log as stated in the procedure manual.
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 the lack of instrument comparison documentation for two BD Bactec FX 40 blood culture instruments and interview with technical supervisor #1, the laboratory failed to evaluate and define a relationship between test results using the same instruments twice a year for 2018, 2019 and to date January 7, 2020. Findings: 1. No documentation was available to show the laboratory evaluated and define a relationship between test results for the BD Bactec FX 40 instrument (A) and BD Bactec FX 40 instrument (C) twice a year for 2018, 2019 and to date January 7, 2020. 2. Interview with technical supervisor #1 on January 7, 2020 at 11:50 AM confirmed the laboratory failed to have a system that twice a year evaluated and defined a relationship between the two blood culture instruments performing the same tests.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 blood gas competencies and interview with technical supervisor #1 the technical consultant failed to evaluate and document six of six annual blood gas competencies in 2018, 2019 and three of three initial blood gas competencies in 2019. Findings: 1. Review of 2018 annual competencies showed the technical consultant failed to evaluate and document competency for testing personnel #1, #2, #3, #5, #6 and #9. 2. . Review of 2019 annual competencies showed the technical consultant failed to evaluate and document competency for testing personnel #1, #2, #3, #5, #6 and #9. 3. Review of 2019 initial competencies showed the technical consultant failed to evaluate and document initial competency for testing personnel #4, #7 and #8. 3. Interview with the technical supervisor #1 on January 7, 2020 at 11:00 AM confirmed the technical consultant failed to evaluate and document blood gas competency in 2018 and 2019.