Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441673	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Scotland County Hospital	450 E Sigler Ave, Memphis, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency and laboratory correlation records for 2016, 2017 and interview with the general supervisor, the laboratory failed to establish a means to verify the accuracy of clostridium difficile(c-Diff), KOH and wet mount testing twice a year. Findings: 1. Review of proficiency records for 2016 and 2017 revealed the laboratory failed to enroll to prove accuracy on the nonregulated analytes c-Diff, KOH, and wet mounts. 2. Review of correlation records for 2016 and 2017 revealed a lack of documentation to prove accuracy 2 times a year for c-Diff, KOH, and wet mounts. 3. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed the laboratory failed to verify the accuracy of the nonregulated c-Diff, KOH, and wet mount testing twice annually for 2016 and 2017.
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 procedure manual and documentation of 2017, 2018 blood bank refrigerator alarm checks and interview with the general supervisor, the

	laboratory failed to follow the procedure for regular alarm inspection checks to ensure temperatures do not exceed the upper limits of safe storage. Findings: 1. Review of the procedure for proper storage of blood and blood products showed " to store blood at 1-6 degrees Celsius(C)." 2. Review of the procedure for performing the blood bank refrigerator alarm check for high activation limits revealed "record the temperature at which the alarm sounds at the high activation temperature (Note: this should be less than 6 degrees C). 3. Review of the documentation for alarm checks for 2017, 2018 revealed the laboratory documented the high end temperatures at 6.1 degrees C for January and May 2017, 6.2 degrees C for October 2017, and 6.1 degrees C for February 2018. 4. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed the laboratory failed to follow the procedure for blood bank refrigerator alarm checks to ensure temperatures do not exceed the upper limits of safe storage.
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 procedure manual revealed and interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed, the laboratory failed to include a step-by-step procedure for usage of blue top tubes on the Ruby complete blood cell analyzer and a step-by-step procedure for detecting weak D antigen in immunohematology testing.
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 manufacturer's instructions, documentation of freezer temperatures and observation of quality control (QC) material stored in the freezer, and interview with the general supervisor, the laboratory failed to follow the manufacturer's instructions for storage of control material for 20 of 26 testing days for June 1, 2018 through June 26, 2018. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquid Multiqual control level I and level III showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 20 degrees C to minus 38 degrees C. 20 of 26 testing days failed to meet the manufacturer's required minus 20 to minus 70 degree C range. 3. Observation of the laboratory freezer showed 4 boxes of Bio-Rad Multiqual level I and III control currently in use in the laboratory. 4. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed the laboratory failed to properly monitor the freezer and store QC material per manufacturer's instructions.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, maintenance documentation, observation of pipettes and interview with the general supervisor, the laboratory failed to define and perform a function check protocol to verify the accuracy of 4 of 4 pipettes. Findings: 1. Review of manufacturer's instructions for the 145 and 280 microliter pipettes used for microbiology testing showed "it is recommended to check the performance of your pipettes regularly and always after in-house maintenance." 2. No documentation was found to show the laboratory defined or performed a function check protocol to verify the accuracy of the volumes of the 145, 280 microliter pipettes used for microbiology testing and the accuracy of the 100 and 200 microliter Finnpipettes used in the detection of Lyme disease. 3. Observation of the 100, 145, 200, 280 microliter pipettes showed no documentation of a function check. 4. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed, the laboratory failed to define a protocol and perform a function check to verify the accuracy of the volumes of 4 of 4 pipettes.
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: Review of calibration records for the Nova Prime blood gas analyzer and the Vidas analyzer for chemistry testing and interview with the general supervisor, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the calibration records for 2017 and to date June 26, 2018 for the analytes: pH, pO2, pCO2, lactic acid and ionized calcium showed the laboratory only performed a two point calibration procedure that included a minimal and maximum value. The calibration kit used in the procedure did not include a mid-point value. 2. Review of the calibration records for 2017 and to date June 26, 2018 for the analytes D-dimer, PCT, and Lyme showed the laboratory failed to perform a calibration with a minimal, mid-point, and maximum value every six months. 3. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed the laboratory failed to include a midpoint calibrator in the calibration verification procedure for blood gas testing on the Nova Prime and chemistry testing on the Vidas analyzer. at least once every six months.
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 manufacturer's instructions, quality control (QC) and patient logs and interview with the general supervisor, the laboratory failed to perform a positive and negative control each day of testing for moderately complex clostridium difficile (c-Diff) kit testing. Findings: 1. Phone interview with client support for Techlab Quik Chek c-Diff kit testing showed the kit is classified as moderate complexity. 2. Review of the quality control logs showed the laboratory failed to perform a positive and negative control each day of testing. 3. Review of the patient logs revealed 37 patient

	results were reported from January 2018 to June 26, 2018. 4. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed, the laboratory did not test a positive and negative control each day of testing and did not complete an IQCP plan to reduce the frequency of testing external controls.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, patient records and interview with the general supervisor, the laboratory failed to follow the manufacturer's instructions for performing weak-D testing. Findings: 1. Review of the manufacturer's instructions showed "weak D describes weaker forms of the D antigen, which may require an indirect antiglobulin test for their detection. Most weak D antigen expressions will be detected as weak positive reactions with this reagent. However, the partial D epitope variant of the D antigen will not be detected with this monoclonal reagent." 2. Review of patient records from January 1, 2018 through June 26, 2018 showed 9 D (Rho) negative cord and 16 D(Rho) negative mother samples were reported. The laboratory did not perform a method to reliably detect weak D(Rho) on the cord blood samples. 3. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed the laboratory failed to follow the instructions for detecting weak D on cord blood samples to determine RhoGam administration to D(Rho) negative mothers.
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 2016, 2017 chemistry comparison records for pH, pCO2, pO2 performed on the Nova Prime and the Abbott i-STAT and interview with the general supervisor, the laboratory failed to perform and evaluate the relationship between the Nova Prime and the Abbott i-STAT twice a year. Findings: 1. Review of comparison records for pH, pO2, pCO2 on the primary analyzer, Nova Prime and the secondary analyzer, Abbott i-STAT, revealed a lack of documentation twice yearly for 2016, 2017. 2. Interview with the general supervisor on June 26, 2018 at 1:00 PM confirmed

	the laboratory failed to perform and document twice a year for 2016, 2017 the comparison of the Abbott i-STAT and Nova Prime for pH, pO2, pCO2.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of quality control(QC) records and interview with the general supervisor. the technical supervisor failed to review QC for Lyme, PCT, and D-dimer testing on the Vidas analyzer. Findings: 1. Review of the QC records for the Vidas analyzer for Lyme, PCT and D-dimer testing for 2017, to date June 26, 2018, revealed the technical supervisor failed to review the records to verify instrument accuracy. 2. Interview with the general supervisor on June 26, 2018 at 1:00PM confirmed the technical supervisor failed to review quality control records.
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 the personnel records for competency evaluations for 2017 and 2018 revealed, and interview with the general supervisor on June 26, 2018 at 1:00PM confirmed, the technical supervisor failed to ensure that 4 of 4 new testing personnel were evaluated semiannually the first year of employment.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel documentation and interview with the general supervisor, the technical supervisor failed to perform 1 of 9 competency evaluations for 2017. Findings: 1. Review of 2017 personnel documentation revealed the technical supervisor failed to perform 1 of 9 competencies for testing personnel of high

	complexity testing. 2. Interview with the general supervisor on June 26, 2018 at 1: 00PM confirmed the technical supervisor failed to perform 1 of 9 annual competencies for 2017.