Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446923	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Texas County Memorial Hospital	1333 S Sam Houston Blvd, Houston, 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 correlation records and interview with the general supervisor on April 3, 2018 at 2:00 PM, the laboratory failed to document and verify accuracy of the non regulated analyte, deoxyhemoglobin, twice annually for 2016 and 2017. 38475 Based on review of laboratories non regulated chemistry verification of accuracy and interview with the general supervisor on April 3, 2018 at 2:00 PM confirmed the laboratory failed to document and verify accuracy of the non regulated analyte Lipase twice annually in 2017.
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 on April 3, 2018 at 3:00 PM confirmed, the procedure manual did not include normal values for cells counted on manual differentials.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the ACL 100 coagulation analyzer, review of manufacturer's instructions (package insert) and interview with the general supervisor, the laboratory failed to follow package insert instructions for using the correct international sensitivity index (ISI) used to calculate to the international normalized ratio (INR). Findings: 1. Observation of the ACL 100 coagulation analzyer showed the laboratory entered and ISI value of 1.04 for thromboplastin reagent lot # N0378719 2. The manufacturer's package insert for thromboplastin reagent lot # N0378719 states an ISI value of 1.06 for the ACL 100 coagulation analzyer. 3. Interview with the general supervisor on April 3, 2018 at 11:30 AM confirmed the laboratory failed to enter the correct ISI value in the coagulation analzyer used to calculate patient INR results.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of quality control (QC) materials (vials) in use for the hematology analyzer, review of manufacturer's instructions and interview with the general supervisor confirmed, the normal control exceeded the expiration date. Findings: 1. Observation of QC material lot # 88801 (normal control) in use April 3, 2018 revealed the vial was opened on March 1, 2018. 2. The manufacturer's instructions state, "open vial stability -14 days." 3. Interview with the general supervisor on April 3, 2018 at 10:00 AM confirmed the laboratory used the normal control past the expiration date.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

	Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the Food and Drug Administration(FDA) website for glucose monitoring devices, manufacturer's insert for the Roche Accu-chek Performa glucometer, procedure manual and interview with the general supervisor, the laboratory failed to verify accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference intervals on a glucometer used "off label"(applications used outside the intended use as specified by the manufacturer's instructions) prior to reporting patient results. Findings: 1. Review of the FDA website for the Roche Accu-Chek Performa glucometer showed the test was listed as General Chemistry Waived. 2. Review of the Roche Accu-Chek Performa manufacturer's insert and manual revealed "the performance of this meter has not been evaluated on critically ill patients". The Roche Accu-Chek Performa manual states"the Accu-Chek Performa Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The system is also not for neonatal use". 3. Interview with the general supervisor and nursing manager on April 3, 2018 at 2:00 PM confirmed the Roche Accu-Chek Performa was used in the ICU on critically ill patients, the neonatal unit and the emergency room on critically ill patients. 4. Review of the laboratory's procedure for the Accu-Chek Performa meter showed the laboratory "purpose" for the meter was "to screen for hypoglycemia/hyperglycemia when there is no reason to suspect that a patient's blood glucose level is below or above the normal range". 5. Interview with the general supervisor on April 3, 2018 at 2:00 PM confirmed the laboratory uses the Accu-Chek Performa meter on critically ill patients, neonatal patients and failed to establish performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, reportable range, and reference intervals prior to patient testing. 38475
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: 38475 Based on review of calibration records for the Vitros 350 chemistry analyzer and the Siemens Rapid Point 500 blood gas analyzer revealed and interview with laboratory staff/general supervisor confirmed, the laboratory failed to perform calibration verification procedures at least once every six months to include 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 the Vitros 350 chemistry analyzer for 2016 and 2017 for the analytes: sodium, potassium and chloride showed the laboratory failed to perform a calibration verification to include a minimal, mid-point and maximum value every 6 months for 2017. 2. Review of the calibration records for the Siemens Rapid Point 500 blood gas analyzer for 2016 and 2017 for the analytes: pH, PO2, PCO2, total hemoglobin, showed the laboratory failed to perform a calibration verification every 6 months for 2017 and for the analytes, oxyhemoglobin, deoxyhemoglobin, methemoglobin and carboxyhemoglobin showed the laboratory failed to perform a calibration verification to include a minimal, mid-point, and maximum value for 2016 and 2017. 3. Interview with laboratory staff/general supervisor on April 3, 2018 at 11:30 AM confirmed the laboratory failed to perform calibration verification for chemistry electrolytes and blood gas testing at least once every six months to include a minimal, mid-point, and maximum value.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the wright stain quality control log for staining white blood cell (WBC) manual differentials and interview with the general supervisor, the laboratory failed to check staining material each day of use. Findings: 1. Review of the wright stain quality control log for January 1, 2017 through March 28, 2018 showed the laboratory checked the stain used for manual WBC differentials on a weekly basis. 2. Interview with the general supervisor on April 3, 2018 at 3:00 PM confirmed the laboratory performs manual differentials on a daily basis and failed to check the staining material on each day of use.
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 instrument comparison activities, laboratory policy and interview with the general supervisor, the laboratory failed to evaluate the relationship between instruments at least twice a year, for same tests performed on different coagulation and troponin instruments for 2017 and to date 2018. Findings: 1. Review of coagulation instrument comparison activities revealed the laboratory performs the same coagulation tests on the ACL Elite (primary) and ACL 100 coagulation instruments (back-up). 2. Review of Biosite instrument comparison activities revealed the laboratory performs troponin and d-dimer testing on two Biosite instruments. The laboratory also performs troponin testing on the Architect instrument. 3. Lab policy # 600-1-1.4 Comparison of Test Results, states, "the laboratory must have a system that twice a year evaluates and defines a relationship between test results for the same analyte using different methodologies, instruments or testing sites. The acceptable difference in these test values at the TCMH lab will be plus or minus ten percent unless otherwise noted." 4. The laboratory did not have documentation to show it evaluated the differences between the instruments performing the same tests and verify comparison activities were within defined limits of performance as stated in the policy. 5. Interview with the general supervisor on April 3, 2018 at 1:00 PM confirmed the laboratory failed to evaluate the results of the instrument comparisons for acceptable performance at least twice a year. 38475 Based on review of Vitros 350 chemistry analyzer, Accu-Chek Performa blood glucose monitoring system and i-Stat chemistry analyzer test comparisons and interview with the general supervisor the laboratory failed to evaluate the relationship between test results on the chemistry analyzers twice a year. Findings: 1. Review of Vitros 350 chemistry analyzer and i-Stat chemistry analyzer showed the Vitros 350 analyzer was the primary analyzer and the i-Stat chemistry analyzer was a back up analyzer. Laboratory failed to evaluate and document the relationship between test results for both analyzers twice a year for sodium, potassium, TCO2, BUN and creatinine. 2. Review of Vitros 350 chemistry analyzer, Accu-Chek Performa blood glucose monitoring system and i-Stat chemistry analyzer showed the laboratory failed to evaluate and document the relationship between tests results for the three analyzers twice a year for the analyte glucose. 3. Interview with the general supervisor on April 3, 2018 at 1:00 PM confirmed the laboratory failed to evaluate the relationship between test results for the chemistry instruments twice a year.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records for 2018, corrective

	action policy and interview with the general supervisor, the laboratory failed to follow the corrective action policy. Findings" 1. Review of QC records for March and April 2018 revealed the hematology instrument failed to analyze and report white blood cell auto differential data on March 24, 2018 at 06:31 AM and April 2, 2018 at 06:49 AM for abnormal QC level II. 2. The corrective action policy states, "the laboratory must perform and document corrective action necessary to ensure reporting of accurate results." 3. No documentation was available to show the laboratory performed and documented corrective action on March 24, 2018 and April 2, 2018 for the analyzer error. 4. Interview with the general supervisor on April 3, 2018 at 3:00 PM confirmed, the laboratory failed to document corrective actions as stated in the laboratory corrective action policy.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: 38475 The director failed to provide overall management and direction of the laboratory by failing to ensure that the test methodologies selected have the capability of providing the quality of results required for patient care (refer to D6085); failed to ensure that the quality control programs are established and maintained (refer to D6093); failed to ensure all testing personnel have the appropriate education, experience and training prior to testing patients' specimens (refer to D6102).
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Roche Accu-Chek Performa glucose meter and interview with general supervisor and chief nursing officer, the laboratory director failed to ensure the test methodology for point of care glucose testing had the capability of providing quality results on critically ill patients and neonatal use. Findings: 1. Review of the Roche Accu-Chek Performa manufacturer's instructions revealed "the performance of this meter has not been evaluated on critically ill patients. This system is also not for neonatal use." 2. No documentation was available to show the laboratory verified performance specifications for off-label (modified) use of the Accu-Chek meters for critically ill patients and neonatal patients. 3. Interview with chief nursing officer on April 3, 2018 at 3:00 PM confirmed the laboratory uses the Accu-Chek meter for critically ill patients and neonatal patients. Interview with the general supervisor on April 3, 2018 at 3:00 PM confirmed, the laboratory did not have documentation to show verification of performance specifications for modified use of the Accu-Chek meters on critically ill patients and neonatal use. Interviews confirmed the director failed to ensure the test methodology provided accurate glucose results for critically ill patients and neonatal patients.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) results for the second event of 2017 and interview with testing personnel #1, the director failed to ensure that proficiency testing failures for blood gas testing were reviewed and remedial actions taken to in order to determine the cause of unsatisfactory performance and to identify any potential negative outcomes. Findings: 1. Review of the second PT event of 2017 showed the laboratory scored a 60 percent for pCO2 with no documentation of the cause of unsatisfactory performance. 2. Review of the second PT event of 2017 revealed the laboratory scored a 80 percent for pO2 of blood gas testing with no documentation of the laboratory's performance. 3. Interview with the testing personnel #1 on April 3, 2017 at 11:30 AM confirmed the director failed to review PT results with unsatisfactory performance.
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(QC) records, QC policy and interview with the general supervisor, the laboratory director failed to review QC for blood gas testing. Findings: 1. Review of the QC records for the Siemens Rapid Point 500 analyzer for blood gas testing for 2017, to date April 3, 2018, revealed the laboratory director failed to review the records since May 9, 2017 to verify instrument accuracy. 2. Review of the QC policy revealed "Monthly data is entered into LabLink (MAS) and reports are reviewed by supervisor and pathologist". 3. Interview with the general supervisor on April 3, 2018 at 3:00PM confirmed the laboratory director failed to review quality control records since May 9, 2017.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the lack of academic credentials and interview with the general supervisor, the director failed to ensure that all personnel had the appropriate education prior to

	patient testing. 1. The laboratory could not provide documentation (academic credentials) to show 3 of 19 testing personnel were qualified to perform blood gas testing and 42 of 42 testing personnel were qualified to perform high complexity point of care glucose testing. 2. Interview with the general supervisor on April 3, 2018 at 2: 30 PM confirmed the documents needed to qualify 3 of 19 testing personnel for blood gas analysis and 42 of 42 testing personnel who perform high complexity point of care glucose testing were not available for review.
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 general supervisor the technical supervisor failed to evaluate and document competency semiannually for one of four new testing personnel for 2016 and 2017. Findings: 1. Review of competencies showed testing personnel #4 did not have competency evaluated and documented semiannually during the first year of testing. 2. Interview with general supervisor on April 4, 2018 at 12:15 PM confirmed the technical supervisor failed to evaluate and document competency semiannually for one of four new testing personnel.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records revealed and interview with general supervisor and nursing administration confirmed, the laboratory failed to have academic qualifications for 42 of 42 testing personnel performing high complexity point of care glucose testing and 3 of 19 testing personnel performing moderate complexity blood gas testing(refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum,

include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on the lack of academic credentials and interview with the general supervisor and chief nursing officer, the laboratory failed to provide academic credentials to qualify 42 of 42 testing personnel performing high complexity point of care glucose testing and 3 of 19 testing personnel performing moderate complexity blood gas analysis. Findings: 1. The laboratory did not have documentation (academic credentials) to show 42 testing personnel were qualified to perform high complexity point of care glucose testing and 3 testing personnel who perform blood gas analysis. 2. Interview with the general supervisor and chief nursing officer on April 3, 2018 at 3:

	00 PM confirmed the documents needed to qualify testing personnel were not available for review on day of survey. 35554