Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652312	04/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cox Barton County Hospital	29 Nw 1st Lane, Lamar, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2019/2020/2021 quality control (QC) records for hematology, and interview with the manager of laboratory services, the laboratory failed to retain quality control records for at least 2 years. Findings: 1. Review of QC records for hematology showed the laboratory failed to retain prothombin-time, partial thromboplastin time and d-dimer QC records for 2019 to August 2020. 2. Interview with the manager of laboratory services on April 14, 2021 at 2:00 PM confirmed the laboratory failed to retain quality control records for at least 2 years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of performance specifications for the Cobas U411 urine analyzer, Alcor Scientific mini iSED, Cerner Laboratory Information System (LIS), function

	check documentation for Thermo Scientific mySPIN 12 mini centrifuge, function check documentation for the HemoCue StatSpin centrifuge, calibration records for the Siemens Dimension EXL chemistry analyzer, calibration records for the Sysmex XS1000i hematology analyzer, Siemens Dimension EXL quality control (QC) records, gram stain QC records, coagulation QC records, Immunohematology procedure manual, and hematology instrument comparisons documentation, the laboratory failed to meet the condition of analytic systems. The laboratory failed to verify performance specifications prior to reporting patient test results for the Cobas U411 urine analyzer, Alcor Scientific mini iSED, and Cerner Laboratory Information System (LIS) (Refer to D5421), failed to perform and document function checks on the Thermo Scientific mySPIN 12 mini centrifuge and the HemoCue StatSpin centrifuge (Refer to D5435), failed to perform a calibration every six months for the Sysmex XS1000i hematology analyzer (Refer to D5437), failed to perform at least a three point calibration (a minimal, mid-point, and maximum) verification every six months for the Siemens Dimension EXL chemistry analyzer (Refer to D5439), failed to ensure alkaline phosphatase (ALP) QC met criteria for acceptability before reporting patient results (Refer to D5481), failed to document positive and negative reactivity each week of use for gram stains (Refer to D5503), failed to include two levels of control material each 8 hours of operation for PT and PTT (Refer to D5545), failed to provide an up-to-date procedure for reviewing patient antibody history (Refer to D5551), failed to correctly perform refrigerator alarm inspections according to the laboratory's established policy (Refer to D5555), and failed to evaluate and define the relationship between hematology test results using two different methodologies twice a year (Refer to D5775).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance specifications for the Cobas U411 urine analyzer, Alcor Scientific mini iSED, Cerner Laboratory Information System (LIS) and interview with the technical supervisor (TS) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Cobas U411 urine analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population. 2. Review of the performance specifications for the Alcor Scientific mini iSED showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population. 3. Review of the performance specifications for the Cerner LIS showed the laboratory failed to verify the LIS performed acceptably before it was integrated into routine operation. 4. Interview with the technical supervisor #1 on April 14, 2021 at 2:00 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.

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 lack of documentation for 2019/2020/2021 function checks and interview with technical supervisor (TS) #1, the laboratory failed to perform and document function checks on the Thermo Scientific mySPIN 12 mini centrifuge and the HemoCue StatSpin centrifuge. Findings: 1. Review of the Thermo Scientific mySPIN 12 mini centrifuge showed no documentation of centrifuge function checks in 2019, 2020 and to date April 14, 2021. 2. Review of the HemoCue StatSpin centrifuge showed no documentation for centrifuge function checks in 2019, 2020 and to date April 14, 2021. 3. Interview with the technical supervisor #1 on April 14, 2021 at 9:30 AM confirmed that the laboratory failed to perform and document function checks in 2019, 2020 and to date April 14, 2021.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of 2019/2020/2021 calibration records for the Sysmex XS1000i hematology analyzer and interview with technical supervisor (TS) #1, the laboratory failed to perform a calibration every six months in 2019. Findings: 1. Review of 2019, 2020 and 2021 calibration records for the Sysmex XS1000i hematology analyzer for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet revealed the laboratory failed to perform a calibration every six months in 2019. 2. Interview with the TS #1 on April 14, 2021 at 2:00 PM confirmed the laboratory failed to perform a calibration of the Sysmex XS1000i hematology analyzer every six months in 2019.
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: Based on review of 2019/2020/2021 calibration records for the Siemens Dimension EXL chemistry analyzer and interview with technical supervisor (TS) #1, the laboratory failed to perform at least a three point calibration (a minimal, mid-point, and maximum) verification every six months. Findings: 1. Review of 2019, 2020 and 2021 calibration records for the Siemens Dimension EXL chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including a minimal, midpoint, and maximum value for each analyte every six months in 2020 and to date April 14, 2021. 2. Interview with the TS #1 on April 14, 2021 at 2:00 PM confirmed the laboratory failed to perform at least a 3 point calibration of the electrolytes on the Siemens Dimension EXL chemistry analyzer every six months.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Siemens Dimension EXL quality control (QC) and interview with testing personnel (TP) #1, the laboratory failed to ensure alkaline phosphatase (ALP) QC met criteria for acceptability before reporting patient results. Findings: 1. Review of ALP QC showed on March 26, 2021 ALP QC level 1 was not within laboratory's acceptability, 16 ALP patient test results were resulted while QC was unacceptable. 2. Review of ALP QC showed on March 30, 2021 ALP QC level 1 was not within laboratory's acceptability, 20 ALP patient test results were resulted while

	QC was unacceptable. 3. Interview with TP #1 on April 14, 2021 at 1:00 PM confirmed the laboratory failed to ensure ALP QC met criteria for acceptability before reporting patient results.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on lack of documentation of gram stain quality control records, interview with testing personnel (TP) #2 and technical supervisor #1, the laboratory failed to document positive and negative reactivity each week of use for gram stains in 2019 /2020/2021. Findings: 1. No documentation of gram stain quality control in 2019, 2020 and to date April 14, 2021. 2. Interview with testing personnel #2 on April 14, 2021 at 1:30 PM, TP #2 stated "They do not record or document gram stain quality control anywhere." 3. Interview with technical supervisor #1 on April 14, 2021 at 1:40 PM confirmed the laboratory failed to document positive and negative reactivity each week of use for gram stains.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 Sysmex CA600 procedure, prothrombin time (PT) quality control (QC), partial thromboplastin time (PTT) QC and interview with the technical supervisor (TS) #1, the laboratory failed to include two levels of control material each 8 hours of operation for PT and PTT. Findings: 1. Review of Sysmex CA600 procedure states "controls should be tested at the initiation of each eight-hour shift". 2. Review of Sysmex CA600 PT QC showed QC was not performed every 8 hours on 1 /15/21. PT QC was performed at 3:45 AM and not again until 2:22 PM. From 11:45 AM until 2:22 PM, 2 patient's were resulted. 2. Review of Sysmex CA600 PT QC showed QC was not performed every 8 hours on 1/21/21. PT QC was performed at 3: 33 AM and not again until 4:37 PM. From 11:33 AM until 4:37 PM, 5 patient's were resulted. 3. Review of Sysmex CA600 PTT QC showed QC was not performed every 8 hours on 1/15/21. PTT QC was performed at 3:45 AM and not again until 2:22 PM. From 11:45 AM until 2:22 PM, 1 patient was resulted. 4. Review of Sysmex CA600 PTT QC showed QC was not performed every 8 hours on 1/21/21. PTT QC was performed at 3:33 AM and not again until 4:37 PM. From 11:33 AM until 4:37 PM, 1 patient was resulted. 5. Review of Sysmex CA600 PT QC showed QC level 2 was completed on 2/11/21, no level 1 control was performed and 1 patient was resulted. 6. Interview with testing personnel #1 on April 14, 2021 at 1:20 PM confirmed the laboratory failed to include two levels of PT and PTT QC material each 8 hours of operation.

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 Immunohematology procedures, interview with testing personnel (TP) #1, TP #3 and manager of laboratory services, the laboratory failed to provide an up-to-date procedure for reviewing patient antibody history. Findings: 1. Review of Immunohematology procedure, "ABO Grouping" states "Patient history is checked every time a sample is received." 2. In August 2020, the laboratory started using Cerner Laboratory Information System (LIS), no previous patient antibody history was uploaded into Cerner LIS from file folders. 3. Interview with testing personnel #1 on April 14, 2021 at 1:00 PM, TP #1 stated that "For patient history, they check both the file folders and then they check the computer for patient antibody history." 4. Interview with testing personnel #3 on April 14, 2021 at 12:50 PM, TP #2 stated that "They used to check the file folders for patient history but now they only check the computer." 5. Interview with manager of laboratory services on April 14, 2021 at 1:15 PM confirmed that the laboratory failed to provide an up-to-date procedure for correctly reviewing patient antibody history.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 the blood bank procedure manual, interview with testing personnel (TP) #3 and technical supervisor (TS) #1, the laboratory failed to correctly perform refrigerator alarm inspections according to the laboratory's established policy. Findings: 1. Review of blood bank procedure, "Alarm Check" states," Immerse the plastic bottle containing the probe in a container of water along with one of the temperature bottles from the refrigerator. Slowly add ice and salt to cool the temperature of the water below 1 C." and "Allow the temperature to return to normal, then slowly add warm water to the container to raise the temperature above 5.5 C." 2. Interview with testing personnel #3 on April 14, 2021 at 10:30 AM, TP stated that "The BioMed department told her to just lower and raise the temperature on the

	refrigerator and freezer by pushing the up and down temperature buttons on the refrigerator and freezer and that she did not need to use cold or warm water any longer." 3. Interview with the technical supervisor #1 on April 14, 2021 at 11:40 AM confirmed, the laboratory failed to correctly perform refrigerator alarm inspections according to the laboratory's established policy.
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 observation of hematology analyzers, lack of hematology instrument comparisons and interview with the technical supervisor (TS) #1, the laboratory failed to evaluate and define the relationship between hematology test results using two different methodologies twice a year in 2019, 2020 and to date April 14, 2021. Findings: 1. Observation of the laboratory revealed a Sysmex XS1000i hematology analyzer and a backup Sysmex KX-21N for performing complete blood counts (CBC). 2. Review of instrument comparisons showed no documentation to evaluate and define the relationship between the Sysmex XS1000i hematology analyzer and a backup Sysmex KX-21N hematology analyzer twice a year in 2019, 2020 and to date April 14, 2021. 3. Interview with the TS #1 on April 14, 2021 at 1:00 PM, confirmed the laboratory failed to evaluate and define the relationship between hematology test results using two different methodologies twice a year in 2019, 2020 and to date April 14, 2021.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of chemistry quality control (QC), hematology QC, bacteriology QC and 2019/2020/2021 personnel performance evaluations, the technical supervisors (TS) failed to fulfill the technical supervisor responsibilities. The technical supervisors failed to provide technical and scientific oversight of the laboratory (Refer to D6112), failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process (Refer to D6117), failed to ensure corrective actions have been taken and the test system is functioning properly prior to resulting patient results (Refer to D6119) and failed to document one of six annual competency evaluations for 2019. (Refer to D6128).
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451

	The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of chemistry, hematology and bacteriology quality control (QC), annual competency, performance specifications and interview with the technical supervisor (TS) #1, the TS's failed to provide technical and scientific oversight of the laboratory. Findings: 1. Review of chemistry, hematology and bacteriology QC showed the TS's failed to ensure the laboratory's established parameters for acceptable levels of analytic performance were maintained throughout the entire testing process (refer to D5545, D5481 and D5551). 2. Review of competencies showed the TS failed to document annual competency for testing personnel #4 in 2019. 3. Review of performance specifications for the Cobas U411 urine analyzer, Alcor Scientific mini iSED and Cerner Laboratory Information System (LIS) showed the TS failed to verify performance specifications prior to reporting patient test results. 4. Interview with the TS #1 on April 14, 2021 at 11:00 AM confirmed the TS's failed to provide technical and scientific oversight of the laboratory.
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 chemistry quality control (QC), hematology QC and interview with the technical supervisor (TS) #1, the TS's failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process. Findings: 1. Review of chemistry QC showed no documentation of review for Siemens Dimension EXL QC from August 2020 to April 14, 2021 to verify instrument accuracy. 2. Review of OPTI CCA-TS blood gas QC showed no documentation of TS review from August 2020 to April 14, 2021 to verify instrument accuracy. 3. Review of Piccolo xpress instrument showed no documentation of TS review of liver panel or basic metabolic panel QC from January 2021 to April 14, 2021 to verify instrument accuracy. 4. Review of hematology QC showed no documentation of TS review for the Sysmex XS1000i QC from August 2020 to April 14, 2021 to verify instrument accuracy. 5. Review hematology QC showed no documentation of TS review for the Sysmex CA600 from August 2020 to April 14, 2021 to verify instrument accuracy. 6. Interview with the TS #1 on April 14, 2021 at 11:00 AM confirmed the TS's failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained throughout the entire testing process.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6)

	The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC), hematology QC and interview with the manager of laboratory services the technical supervisors (TS) failed to ensure corrective actions have been taken and the test system is functioning properly prior to resulting patient results. Findings: 1. Review of ALP QC showed on March 26, 2021 ALP QC level 1 was not within laboratory's acceptability, 16 ALP patient test results were reported out with no documentation of corrective action. On March 30, 2021 ALP QC level 1 was not within laboratory's acceptability, 20 ALP patient test results were reported out with no documentation of corrective action. 2. Review of hematology QC for prothrombin time (PT) and partial thromboplastin time (PTT) showed controls were not completed according to the laboratory procedure "controls should be tested at the initiation of each eight-hour shift". The laboratory failed to document corrective action on the days QC was not completed every eight hours. 3. Interview with the manager of laboratory services on April 14, 2021 at 12:15 PM confirmed the TS's failed to ensure corrective actions have been taken and the test system is functioning properly prior to resulting patient test results.
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 2019/2020/2021 personnel performance evaluations and interview with the technical supervisor #1, the technical supervisors failed to document one of six annual competency evaluations for 2019. Findings: 1. Review of 2019 personnel competency evaluations revealed the technical supervisors failed to document annual competency for testing personnel #4. 2. Interview with the technical supervisor #1 on April 14, 2021 at 12:00 PM confirmed the technical supervisors failed to document annual competency for testing personnel #4 in 2019.