Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652312	03/06/2023
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records for 2022 and to date March 1, 2023, and interview with the technical supervisor (TS) #2, the laboratory failed to enroll in an approved PT program for the sub-specialty of Bacteriology listed in subpart I. Findings: 1. Review of 2022 and to date March 1, 2023 PT records showed no enrollment in an approved PT program for the analyte: gram stain. 2. Interview with the TS #2 on March 1, 2023, at 2:30 PM confirmed the laboratory failed to enroll in an approved PT program for the sub-specialty of Bacteriology.
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 blood bank temperature logs, calibration records for the Dimension EXL w/LM Chemistry analyzer, calibration records for the Sysmex KX21N Hematology Analyzer, Gram stain quality control (QC) logs, blood bank QC, and blood bank alarm checks; the laboratory failed to review "BB Temp logs" (D5413); failed to perform calibration verification procedures at least once every 6 months to include minimum point, mid-point, and upper limit for sodium, potassium, and chloride on the chemistry analyzer and all analytes on the hematology analyzer (D5439); failed to perform weekly gram stain quality controls (D5503); failed to document blood bank QC for all days of patient testing (D5551) and the laboratory failed to perform 2 of 7 blood bank refrigerator and freezer alarm checks (D5555).
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 blood bank continuous monitoring temperature logs and interview with technical supervisor (TS) #2, the laboratory failed to document continuous temperature monitoring and document when temperatures were outside of acceptable range for the refrigerator and freezer in blood bank. Findings: 1. Review of blood bank continuous monitoring temperature logs showed the laboratory failed to have the temperature continually monitored at the following times: February 10, 2021 at 12:00 PM to February 11, 2021 at 1:30 PM no temperature reading for the refrigerator December 1, 2021 at 12:00 PM to December 3, 2021 at 3:00 AM no temperature reading for the refrigerator December 21, 2022 at 12:00 PM to December 22, 2022 at 6:00 AM, no temperature reading for refrigerator and freezer 2. Review of blood bank continuous monitoring logs showed the laboratory failed to document when the temperature were outside of acceptable range for the refrigerator and freezer in blood bank for the following dates: January 27, 2021 July 29, 2021 October 28, 2021 May 20, 2022 3. Interview with the TS #2 on March 1, 2023 at 1:00 PM confirmed the laboratory failed to document continuous temperature monitoring and document reasons for fluctuations in temperature monitoring for the refrigerator and freezer in blood bank.
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 calibration records for the Sysmex KX21N hematology analyzer, review of calibration verification documentation for the Dimension EXL w/LM chemistry analyzer, and interview with the technical supervisor (TS) #2, 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 on the Dimension EXL -200 chemistry analyzer and on the Sysmex KX21N hematology analyzer. Findings: 1. Review of the Sysmex KX21N hematology analyzer calibration records for 2021, 2022 and to date March 1, 2023 showed no calibration for December 2021 and June 2022 for the following analytes; white blood count, red blood count, hemoglobin, hematocrit, and platelets. Documentation provided for calibration performed December 2022. 2. Review of Dimension EXL w/LM chemistry analyzer calibration records for 2021 to date March 3, 2023 showed no calibration 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 for the analytes: sodium, potassium and chloride. 3. Interview with TS #2 on March 1, 2023 at 1:00 PM confirmed 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 on the Dimension EXL -200 chemistry analyzer and on the Sysmex KX21N hematology analyzer.
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 review of patient gram stain logs, gram stain quality control (QC) logs, and interview with the technical supervisor (TS) #2, the laboratory failed to perform a positive and negative QC each week. Findings: 1. Review of gram stain QC logs showed "frequency: Daily with patient testing". 2. Review of patient gram stain logs showed one gram stain was performed on January 24, 2023 and no QC was documented. The laboratory could not provide patient gram stain logs for 2021 and

	2022. 3. Review of 2021 and 2022 gram stain QC logs showed no gram stain QC weekly on: June 21, 2021 July 25, 2021 August 1, 2021 August 8, 2021 August 21, 2021 September 27, 2021 October 8, 2021 October 19, 2021 October 28, 2021 November 1, 2021 November 8, 2021 December 13, 2021 January 11, 2022 January 28, 2022 February 1, 2022 March 9, 2022 April 22, 2022 May 22, 2022 June 1, 2022 June 8, 2022 June 15, 2022 June 28, 2022 July 19, 2022 August 10, 2022 August 26, 2022 September 27, 2022 October 24, 2022 4. Interview with the TS #2 on March 1, 2023 at 1:00 PM confirmed the laboratory failed to perform a positive and negative gram stain QC each week.
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 blood bank procedures, blood bank patient logs for 14 of 26 months, blood bank quality control (QC) logs for 14 of 26 months, and interview with the technical supervisor (TS) #2, the laboratory failed to document quality control (QC) for fourteen patient testing days. Findings: 1. Review of the laboratory's blood bank procedure "Reagent Quality Control" states, "Reagents need quality control run on days that patient samples are being run." 2. Review of blood bank patient testing logs showed patient testing was performed on June 7, 2021, June 28, 2021, October 7, 2021, November 30, 2021, December 16, 2021, December 19, 2021, January 4, 2022, January 18, 2022, January 23, 2022, January 29, 2022, March 11, 2022, May 2, 2022, September 20, 2022, and January 20, 2023. 3. Review of blood bank QC logs showed no documented QC on June 7, 2021, June 28, 2021, October 7, 2021, November 30, 2021, December 16, 2021, December 19, 2021, January 4, 2022, January 18, 2022, January 23, 2022, January 29, 2022, March 11, 2022, May 2, 2022, September 20, 2022, and January 20, 2023. 4. Interview with the TS #2 on March 1, 2023 at 2:30 PM, confirmed the laboratory failed to document quality control for 14 patient testing days.
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 blood bank "high/low alarm testing worksheet", and interview with the technical supervisor (TS) #2, the laboratory failed to perform 2 of 7 refrigerator and freezer alarm inspections. Findings: 1. Review of refrigerator and freezer blood bank alarm testing worksheet showed no refrigerator alarm inspections for second and third quarter 2021. 3. Interview with the TS #2 on March 1, 2023 at 10: 00 AM confirmed, the laboratory failed to perform blood bank refrigerator and freezer alarm inspections.
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: Based on review of proficiency testing (PT) results in 2021/2022 and review of quality control, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure the laboratory was enrolled in PT for Gram Stains (D6088); failed to ensure the appropriate staff evaluated ungraded PT results in 2022 (D6091); and failed to ensure quality control programs are maintained (D6093).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2022 and to date March 1, 2023 and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to ensure the laboratory was enrolled in an approved PT program for the sub-specialty of Bacteriology listed in subpart I. Findings: 1. Review of PT records for 2022 and to date March 1, 2023 showed the LD failed to ensure that gram stain testing was enrolled in an approved PT program for the sub-specialty of Bacteriology listed in subpart I. 2. Interview with the TS #2 confirmed the laboratory director (LD) failed to ensure the laboratory was enrolled in an approved PT program for the sub-specialty of Bacteriology listed in subpart I.
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 testing (PT) records and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure appropriate staff evaluated ungraded PT results in 2022. Findings: 1. Review of UDS-C 2022 PT results revealed sample methamphetamine UDS-12 was not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded UDS-12. 2. Review of CAR-C 2022 PT results revealed sample troponin HCR-15 was not graded by the PT provider. The laboratory did not have documentation to show appropriate staff evaluated the ungraded HCR-15. 3. Interview with TS #2 on March 1, 2023 at 1:30 PM confirmed the laboratory director failed to ensure appropriate staff evaluated the ungraded results.
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 blood bank quality control (QC), instrument calibrations and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure quality control programs are maintained. Findings: 1. Review of blood bank patient testing logs showed patient testing was performed on June 7, 2021, June 28, 2021, October 7, 2021, November 30, 2021, December 16, 2021, December 19, 2021, January 4, 2022, January 18, 2022, January 23, 2022, January 29, 2022, March 11, 2022, May 2, 2022, September 20, 2022, January 20, 2023 and no QC was documented. 2. Review of calibration verification showed calibration verification was not performed 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 on the Dimension EXL -200 chemistry analyzer and the Sysmex KX21N hematology analyzer. 3. Interview with the TS #2 on March 1, 2023 at 1:30 PM confirmed the laboratory director failed to ensure quality control programs are maintained.
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 personnel records and interview with the technical supervisor (TS) #2, the TS failed to evaluate and document the performance of one of two testing personnel (TP) at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of 2021 and 2022 performance evaluations showed the TS failed to perform the semi-annual competency evaluation in blood bank for TP #5. 2. Interview with the TS #2 on March 1, 2023 at 1:00 PM, confirmed the TS failed to evaluate and document the performance of one of two TP at least semiannually during the first year the individual tests patient specimens.

D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) and interview with the technical supervisor (TS) #2, the laboratory could not access PT records and data within a reasonable time frame during the course of the inspection.