Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652312	10/08/2024
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, interview with the laboratory consultant, and interview with the technical supervisor (TS) #6, the laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens. Findings: 1. Review of the the laboratory procedure "Proficiency Testing Program" states "A final check for clerical errors is performed by another testing personnel and documented." 2. Interview with the laboratory consultant on October 8, 2024 at 1:00 PM stated "They do not perform a final clerical check for patients prior to reporting results." 3. Interview with the technical supervisor (TS) #6 on October 8, 2024 at 1:30 PM confirmed the laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens.
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 procedures for the Sysmex XN-550 hematology analyzer, performance specifications procedures for the iSTAT blood gas analyzer, laboratory's submitted CMS 116 form, and interview with the technical supervisor (TS) #6, the laboratory failed to verify performance specifications prior to reporting patient test results in 2023. Findings: 1. Review of the performance specifications for the Sysmex XN-550 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell, hematocrit, hemoglobin, white blood cell, platelet count and differential prior to patient testing in June 2023. 2. Review of the performance specifications for the iSTAT blood gas analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: pH, pCO2, pO2, and lactate prior to patient testing in April 2023. 3. Review of the laboratory's submitted CMS 116 form showed the laboratory performs approximately 90,344 hematology tests and approximately 186,816 chemistry tests annually. 4. Interview with the technical supervisor #6 on October 8, 2024 at 1:30 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results on the Sysmex XN-550 hematology analyzer, and the iSTAT blood gas analyzer.
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 the Clostridium difficile (C.diff) Quik Chek Complete kit test quality control (QC) records for 2023 to date October 8, 2023, patient results and interview with the technical supervisor (TS) #6, the laboratory failed to perform positive and negative controls for C.diff for 138 of 144 patient testing days. Findings: 1. Review of C.diff Quik Chek Complete kit test QC records from February 2023 to date October 8, 2024 showed the laboratory failed to perform a positive and negative QC for 138 of 144 patient testing days. 2. Review of patient results showed the laboratory performed 166 C.diff patient tests while QC was not performed. 3. Interview with the technical supervisor #6 on October 8, 2024 at 1:30 PM confirmed the laboratory failed to perform a positive and negative control each day of patient testing.
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 gram stain quality control (QC) records, and interview with technical supervisor #6, the laboratory failed to document positive and negative reactivity each week of use for gram stains for 1 of 28 weeks. Findings: 1. Review of gram stain QC showed no gram stain QC performed the week of October 16, 2023. 2. Interview with the technical supervisor #6 on October 8, 2024 at 1:30 PM confirmed the laboratory failed to document positive and negative reactivity each week of use for gram stains.
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 laboratory analyzers, review of instrument comparisons, and interview with the technical supervisor (TS) #6, the laboratory failed to evaluate and define the relationship between test results using different instruments two times a year in 2023. Findings: 1. Observation of laboratory analyzers revealed two iStat analyzers that perform pH, pCO2, and PO2. 2. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzers twice a year in 2023. 3. Review of laboratory analyzers revealed iStat analyzer and Siemens Dimension EXL 200 analyzer that perform lactic. 4. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the iStat analyzer and Siemens Dimension EXL 200 analyzer twice a year in 2023. 5. Interview with the TS #6 on October 8, 2024 at 1:30 PM, confirmed the laboratory failed to evaluate and define the relationship between test results using different instruments two times a year in 2023.
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 the Siemens Dimension EXL 200 chemistry analyzer quality control (QC) records for alkaline phosphatase and interview with the technical supervisor (TS) #6, the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. Review of the Siemens Dimension EXL 200 QC records showed the laboratory used unassayed ChemTrak QC. The laboratory started

	a new lot number CHU25121 of QC in August 2024. 2. Review of assayed QC on the Siemens Dimension EXL 200 analyzer showed alkaline phosphatase level 1 QC range of 38-52. 3. Review of QC revealed alkaline phosphatase QC was accepted and the QC values did flag as "L" in the computer on the following date: August 9, 2024 alkaline phosphatase level 1 QC results 36, 34, 35, and 37 all 4 results were flagged as "L". The laboratory could not provide documentation of why QC was accepted when results were not within established acceptable limits. 4. Review of QC revealed alkaline phosphatase QC was flagged as "H" in the computer on the following dates but QC results were within the acceptable range: August 10, 2024 alkaline phosphatase level 1 QC result 41 and 38 August 11, 2024 alkaline phosphatase level 1 QC result 42 and 43 August 12, 2024 alkaline phosphatase level 1 QC result 45, 46, 39 and 43 The laboratory could not provide documentation of why QC was flagging "H" but was within established acceptable limits. 5. Review of QC revealed alkaline phosphatase QC was accepted and the QC values did not flag in the computer on the following dates but QC results were not within the acceptable range: August 10, 2024 alkaline phosphatase level 1 QC result 34 August 11, 2024 alkaline phosphatase level 1 QC result 35 August 12, 2024 alkaline phosphatase level 1 QC result 35 The laboratory could not provide documentation of why QC was accepted when results were not within established acceptable limits. 6. Interview with the TS #6 on October 8, 2024 at 1:30 PM confirmed the laboratory director failed to ensure the quality control program was maintained to assure the quality of laboratory services and to identify failures in quality as they occur.