Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046095	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cameron Regional Medical Center	1600 E Evergreen, Cameron, 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**
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 procedures, review of Biomerieux Vidas 3 analyzer manufacturer's instructions, review of procalcitonin calibrations, observation of Modified Thayer Martin culture plates, observation of the microbiological safety cabinet, review of 2019/2020/2021 calibration records for the Sysmex XN-1000 and Sysmex KX-21N hematology analyzers, review of Individualized Quality Control Plan (IQCP) for AmniSure Rupture of Fetal Membranes (ROM) Test, IQCP for Vitek microbiology analyzer, AmniSure ROM Test package insert, 2020/2021 quality control (QC) records, observation of Sysmex XN1000 hematology analyzer, review of hematology QC, review of the "Quality Assurance Program" procedure, "Chemistry Quality Control" procedure, and Siemens Dimension EXL chemistry analyzer QC, the laboratory failed to meet the condition of analytic systems. The laboratory failed to have a written procedure for performing blue top tube's on the Sysmex SN1000 and a procedure for the Vidas Biomerieux 3 analyzer. (Refer to D5401); failed to follow manufacturer's instructions for procalcitonin calibrations (Refer to D5411); failed to discard expired Modified Thayer Martin culture (Refer to D5417); failed to perform and document maintenance for the microbiological safety cabinet in 2019/2020 (Refer to D5429); failed to follow manufacturer's recommended frequency for calibration of hematology analyzers in 2019/2020 (Refer to D5437); laboratory failed to include a risk assessment and an acceptable Quality Control Plan (QCP) (Refer to D5445);

	laboratory failed to perform a negative and positive control each day of patient testing for AmniSure ROM Test from January 2020 to date, April 28, 2021 (Refer to D5449); laboratory failed to ensure the established criteria for acceptability of controls was followed by laboratory personnel (Refer to D5469); laboratory failed to establish written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (Refer to D5791).
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 procedures and interview with technical supervisor (TS) #2, the laboratory failed to have a written procedure for performing blue top tubes on the Sysmex SN1000 and a procedure for the Vidas Biomerieux 3 analyzer. Findings: 1. Review of Sysmex XN1000 showed no blue top tube procedure available for the laboratory personnel. 2. Review of the Vidas Biomerieux 3 analyzer showed no procedure for procalcitonin available for the laboratory personnel. 3. Interview April 28, 2021 at 12:15 PM with TS #2 confirmed the laboratory failed to have written procedures for blue top tubes on the Sysmex XN1000 and the procalcitonin analyte on the Vidas Biomerieux 3 analyzer.
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 review of Biomerieux Vidas 3 analyzer manufacturer's instructions, review of procalcitonin calibrations and interview with testing personnel (TP) #5, the laboratory failed to follow manufacturer's instructions for procalcitonin calibrations. Findings: 1. Review of Biomerieux Vidas 3 analyzer manufacturer's instructions for procalcitonin states "calibration, using the two calibrators provided in the kit, must be performed each time a new lot of reagents is opened, after the master lot data (MLE) has been entered, and then every 28 days". 2. Review of procalcitonin calibrations showed a calibration was due on: May 10, 2020, no patients were resulted, calibration was not performed until May 15, 2020. June 12, 2020, no patients were resulted, calibration was not performed until June 21, 2020. September 16, 2020, no patients were resulted, calibration was not performed until September 18, 2020. December 1, 2020, no patients were resulted, calibration was not performed until December 10, 2021. January 7, 2021, four patients were resulted, calibration was not performed until January 25, 2021. 3. Interview on April 28, 2021 at 11:00 AM with the TP #5 confirmed the laboratory failed to follow manufacturer's instructions for procalcitonin calibrations.

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 Modified Thayer Martin culture plates, and interview with the general supervisor (GS) #1, the laboratory failed to discard expired Modified Thayer Martin culture plates. Findings: 1. Observation of Modified Thayer Martin culture plates showed: Four packages of Modified Thayer Martin lot # 478495, expiration date April 13, 2021 still in use. 2. Interview with the GS #1 on April 28, 2021 at 12:15 PM confirmed the laboratory failed to discard expired Modified Thayer Martin culture plates.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the microbiological safety hood and interview with the general supervisor (GS) #1, the laboratory failed to define, perform and document maintenance for the microbiological safety hood in 2019/2020. Findings: 1. Observation of the microbiological safety hood showed no documentation of maintenance for the microbiological safety cabinet in 2019/2020. The laboratory could not provide documentation defining the frequency of microbiological safety hood maintenance. 2. Interview with the GS #1 on April 28, 2021 at 1:00 PM confirmed, the laboratory failed to perform and document maintenance for the microbiological safety hood in 2019/2020.
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 XN-1000 and

	Sysmex KX-21N hematology analyzers and interview with technical supervisor (TS) #2, the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of hematology analyzers in 2019/2020. Findings: 1. Review of 2019, 2020 and 2021 calibration records for the Sysmex XN-1000 hematology analyzer showed the laboratory failed to perform a calibration for the Sysmex XN-1000 following manufacturer's recommended frequency of every six months in 2019 /2020 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 2. Review of 2019, 2020 and 2021 calibration records for the Sysmex KX-21N hematology analyzer showed the laboratory failed to perform a calibration for the Sysmex KX-21N following manufacturer's recommended frequency of every six months in 2019/2020 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 3. Interview with the TS #2 on April 28, 2021 at 1:00 PM confirmed the laboratory failed to follow manufacturer's recommended frequency of every six months for calibration of the Sysmex XN-1000 and Sysmex KX-21N hematology analyzers in 2019/2020.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Individualized Quality Control Plan (IQCP) for AmniSure Rupture of Fetal Membranes (ROM) Test, IQCP for Vitek microbiology analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to include a risk assessment and an acceptable Quality Control Plan (QCP). Findings: 1. Review of IQCP for AmniSure ROM Test showed a risk assessment that did not include identification and evaluation of potential failures and sources of errors in the testing system. 2. Review of IQCP for AmniSure ROM Test showed the QCP did not include the frequency for testing quality control material. 3. Review of IQCP for Vitek microbiology analyzer showed a risk assessment that did not include identification and evaluation of potential failures and sources of errors in the testing system. 4. Review of IQCP for Vitek microbiology analyzer showed the QCP did not include the frequency for testing quality control material. 5. Interview with the TS #2 on April 28, 2021 at 11:30 AM confirmed the laboratory failed to include an acceptable risk assessment and QCP for AmniSure ROM Test and the Vitek microbiology 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 AmniSure ROM Test package insert, 2020/2021 quality control (QC) records, and interview with the technical supervisor (TS) #2, the laboratory failed to perform a negative and positive control each day of patient testing from January 2020 to date, April 28, 2021. Findings: 1. Review of AmniSure ROM Test package insert states that "It is recommended to use external controls and to follow federal, state, and local guidelines for quality control requirements". 2. Review of 2020/2021 QC records showed the laboratory failed to perform a negative and positive control each day of patient testing from January 2020 to date, April 28, 2021. The laboratory could not provide documentation of dates and volumes of patient testing performed. 3. Interview with the TS #2 on April 28, 2021 at 11:30 AM confirmed the laboratory failed to perform a negative and positive control each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of Sysmex XN1000 hematology analyzer, review of hematology quality control (QC), and interview with the technical supervisor (TS) #2, the laboratory failed to ensure the established criteria for acceptability of controls was followed by the laboratory personnel. Findings: 1. Observation of the Sysmex XN1000 hematology analyzer showed QC ranges in the analyzer from November 9, 2020 to date April 28, 2021 as: QC Level 1: RBC 0.00-4.74 HGB 0.0-11.8 HCT 0.0-34.8 MCV 0.0-147.2 MCH 0.0-50.0 MCHC 0.0-67.8 PLT 0-172 QC Level 2: RBC 0.00-8.78 HGB 0.0-25.2 HCT 0.0-74.0 MCV 0.0-168.6 MCH 0.0-57.4 MCHC 0.0-68.0 PLT 0-490 QC Level 3: RBC 0.00-10.78 HGB 0.0-32.8 HCT 0.0-95.2 MCV 0.0-88.4 MCH 0.0-60.8 MCHC 0.0-68.8 PLT 0-1094 2. Review of Sysmex XN1000 QC package insert showed: QC Level 1: RBC: 2.21-2.44 HGB: 5.5-6.1 HCT: 16.0-18.4 MCV: 69.4-78.2 MCH: 22.9-26.9 MCHC: 30.3-37.1 PLT: 56-124 QC level 2: RBC: 4.20-4.55 HGB: 12.1-13.1 HCT: 34.5-38.9 MCV: 78.8-88.8 MCH: 26.8-30.8 MCHC: 31.2-37.4 PLT: 224-280 QC Level 3: RBC: 5.1-5.52 HGB: 15.8-17.1 HCT: 43.8-49.4 MCV: 82.5-93.1 MCH: 29.1-32.8 MCHC: 32.4-38.1 PLT: 507-608 3. Interview on April 28, 2021 at 11:30 AM with the TS #2 confirmed the laboratory failed to ensure the established criteria for acceptability of Sysmex XN1000 controls was followed by the laboratory personnel.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the "Quality Assurance Program" procedure, "Chemistry Quality Control" procedure, Siemens Dimension EXL chemistry analyzer quality control (QC) and interview with the technical supervisor (TS) #2, the laboratory failed to establish written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings: 1. Review of the "Quality Assurance Program" procedure states "If a difference is seen in quality control values, affected patient results should be reanalyzed". The quality assurance procedure did not define the meaning of the statement "difference is seen in quality control values" in order for laboratory personnel to identify problems in the analytic system. 2. Review of "Chemistry Quality Control" procedures states "After the analysis has been completed, check the results in the computer to make sure all results are within 2 standard deviations. When using two levels of control, one level can be within 3 standard deviations as long and the other is within 2 standard deviations." The procedure did not include an ongoing mechanism to monitor and assess QC over 2 SD. 3. Review of alkaline phosphatase (ALKP) level 1 QC: April 8, 2021 level 1 QC was greater than 2 standard deviations (SD) and QC repeated. April 9, 2021 level 1 QC was greater than 2 SD and QC repeated. April 11, 2021 level 1 QC was greater than 2 SD and laboratory personnel did not repeat the control and no documentation. April 14, 2021 level 1 QC was greater than 2 SD and QC repeated April 15, 2021 level 1 QC was greater than 2 SD, and QC repeated. April 16, 2021 level 1 QC was greater than 2 SD, and QC repeated. The laboratory could not provide a written procedure on when to repeat QC, what to do if QC is trending high or low and how many days QC could be out 2 SD before patient testing is stopped. 4. Review of ALKP QC showed no documentation when QC was trending high. On April 7, 8,10, 11, 14, 15 and 16 QC level 1 was trending high with no documentation. 5. Interview with the TS #2 on April 28, 2021 at 12:30 PM confirmed the laboratory failed to establish written procedures for an ongoing mechanism to monitor assess, and when indicated, correct problems identified in the analytic systems.