Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0046095	08/21/2018
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the specimen rejection criteria policy and interview with testing personnel #1, the laboratory failed to establish criteria for specimen acceptability and rejection of bacteriology specimens Findings: 1. The specimen rejection criteria policy states, "criteria for specimen rejection are dependent on individual tests." 2. The specimen rejection criteria policy did not include criteria for specimen acceptability and rejection of bacteriology specimens for culture and sensitivity testing. 3. Interview with testing personnel #1 on August 21, 2018 at 11:00 AM confirmed the policy did not include specimen acceptability and rejection criteria required for processing bacteriology specimens for testing.
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 and interview with testing personnel # 7 on August 21, 2018 at 10:30 AM confirmed, the laboratory failed to include at least a minimal (or zero) value, a mid-point value and a maximum value to verify the laboratory's reportable range at least once every six months during 2017 and to date August 21, 2018 for the sodium, potassium and chloride analytes.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control documents for bacteriology and interview with technical supervisor revealed the laboratory failed to check each batch of blood agar, McConkey agar, MacConkey Biplate and Bactec blood culture media for its ability to support growth and as appropriate, select or inhibit specific organisms. Findings: 1. Review of QC logs showed the laboratory failed to check each batch of blood agar, McConkey Biplate, MacConkey agar and Bactec blood culture media for its ability to support growth. 2. Interview with the technical supervisor on August 21, 2018 at 10: 00 AM confirmed the laboratory failed to check each batch of blood agar, McConkey agar, MacConkey Biplate and Bactec blood culture media for its ability to support growth.