Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0678066	09/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Crmc Abg Lab	1600 E Evergreen (Respiratory), 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
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 laboratory procedures and interview with the testing personnel (TP) #1, the laboratory failed to ensure a written procedure is available for evaluating competency, blood gas panic values, and proficiency testing performance. Findings: 1. Review of laboratory procedures showed no procedure for evaluating competency, reporting and documenting blood gas panic values, and evaluating proficiency testing performance and identify any problems that require corrective action. 2. Interview with the TP #1 on September 10, 2024 at 11:00 AM confirmed the laboratory failed to ensure a written procedure for evaluating competency, blood gas panic values, and blood gas panic values, and proficiency testing performance is available.
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 performance verification procedures for the Siemens Rapid Point 500 E blood gas analyzer and interview with testing personnel (TP) #1, the laboratory failed to verify reference intervals (normal values) prior to reporting patient results. Findings 1. Review of the laboratory's performance verification procedures for the Siemens Rapid Point 500 E blood gas analyzer showed the laboratory failed to perform the normal range study for the measured analytes: pH, PCO2, PO2, THb, O2Hb, COHb, MetHb, HHb, sodium, potassium, calcium, chloride, glucose, and lactic acid prior to the beginning of patient testing in July 2024. 2. Interview with TP #1 on September 10, 2024 at 11:00 AM confirmed the laboratory failed to perform verification of normal ranges for the Siemens Rapid Point 500 E blood gas analyzer.
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 2022, 2023, and to date September 10, 2024 calibration records on the EPOCH blood gas analyzer for 9 of 9 analytes and interview with testing personnel (TP) #1, 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. Findings: 1. Review of EPOCH calibration records showed no calibration every six months that include 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 PO2, PCO2, pH, sodium, potassium, ionized calcium, chloride, glucose, and lactate. 2. Interview with the TP #1 on September 10, 2024 at 11:00 AM 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.
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 testing personnel (TP) #1, the laboratory failed to evaluate and define the relationship between test results using different instruments two times a year in 2022 and 2023. Findings: 1. Observation of laboratory analyzers revealed an EPOCH analyzer and a Siemens Rapid Point 500e, both analyzers perform pH, pCO2, PO2, sodium, potassium, chloride, ionized calcium, glucose, and lactate. 2. Review of instrument comparisons showed the laboratory had no documentation to evaluate and define the relationship between the EPOCH analyzer and the Siemens Rapid Point 500e analyzer twice a year in 2022 and 2023. 3. Interview with the TP #1 on September 10, 2024 at 10:00 AM, confirmed the laboratory failed to evaluate and define the relationship between blood gas test results using different instruments two times a year in 2022 and 2023.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of patient blood gas results, lack of documentation of notifying individual responsible for test results, and interview with the testing personnel (TP) #1, the laboratory failed to immediately alert the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic values. Findings: 1. Review of patient blood gas test reports showed patient tested on June 22, 2024 at 6:58 AM with a panic pH value of 7.169 and a panic lactic acid value of 5. 2. Lack of documentation showed the laboratory failed to immediately alert the individual responsible for using the panic pH and lactic acid values. 3. Interview with the TP #1 on September 10, 2024 at 11:00 AM confirmed the laboratory failed to immediately alert individuals responsible for panic pH and lactic acid values.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 the 2023 and to date September 10, 2024 proficiency testing (PT) records and interview with the testing personnel (TP) #1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of the 2024 Blood Gas2 proficiency testing event showed the laboratory obtained a "Not Graded" result for all samples for the analyte Chloride. The laboratory could not provide documentation to show appropriate staff evaluated the "Not Graded" results to identify any problems that may require corrective action. 2. Interview with TP #1 on September 10, 2024 at 11:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.