Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0678066	11/15/2022
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of 2021 and 2022 proficiency testing (PT) results and interview with technical consultant (TC) #2, the laboratory failed to verify the accuracy of analytes that are not evaluated or scored by a CMS-approved PT program. Findings: 1. Review of "WSLH PT 2021-Blood Gas 1" PT results showed the analyte chloride was "not scored-non consensus" and the laboratory failed to evaluate. 2. Interview with the TC #2 on November 15, 2022 at 12:30 PM confirmed the laboratory failed to verify the accuracy of PT event 2021 Blood gas 1 for the analyte chloride that was not evaluated or scored by a CMS-approved PT program.
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 EPOC blood gas procedure, EPOC calibration verification and

	EPOC blood gas quality control (QC), lack of calibration records for the EPOC blood gas analyzer and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to ensure a written procedure is available for the EPOC blood gas analyzer (Refer to D5401); the laboratory failed to test one sample of control material each 8 hours of testing (Refer to D5537), and 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 for 2021 and to date November 15, 2022 (Refer to D5439).
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 technical consultant (TC) #2, the laboratory failed to ensure a written procedure is available for the EPOC blood gas analyzer. Findings: 1. Review of laboratory procedures showed no procedure for the EPOC blood gas analyzer. 2. Interview with the TC #2 on November 15, 2022 at 12:00 PM confirmed the laboratory failed to ensure a written procedure for the EPOC blood gas analyzer is available.
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 lack of calibration records for the EPOC blood gas analyzer and interview

	with the technical consultant (TC) #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 for 2021 and to date November 15, 2022. Findings: 1. Lack of calibration records for the EPOC blood gas analyzer for 2021 and to date November 15, 2022 showed no calibration 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: pH, pCO2 and pO2, sodium, potassium, chloride, ionized calcium, total CO2, glucose and lactic acid. 2. Interview with the TC #2 on November 15, 2022 at 12:00 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 for pH, pCO2 and pO2, sodium, potassium, chloride, ionized calcium, total CO2, glucose and lactic acid.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of 2021 and to date November 15, 2022 EPOC blood gas quality control (QC) and interview with the technical consultant (TC) #2, the laboratory failed to test one sample of control material each 8 hours of testing. Findings: 1. Review of the EPOC blood gas QC showed the laboratory did not perform blood gas QC every 8 hours of patient testing in 2021 and to date November 15, 2022. 2. Interview with the TC #2 on November 15, 2022 at 12:00 PM confirmed the laboratory failed to test one sample of blood gas control material each 8 hours of testing.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Siemens Rapid Point 500 blood gas analyzer quality control, proficiency testing and interviews, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to 6018); failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory (Refer to 6019); failed to ensure the QC program is established and maintained to assure the quality of the laboratory services (Refer to 6020); and failed to ensure the QC and quality assesment program is established and maintained to identify failures in quality as they occur (Refer to 6022).

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 2021 and 2022 proficiency testing (PT) and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for two of five events in 2021 and 2022. Findings: 1. Review of WSLH PT results event 2021-Blood Gas 3 and event 2022-Blood Gas 2 showed no review by the appropriate staff to evaluate the laboratory's performance. 2. Interview with the TC #2 on November 15, 2022 at 12:30 PM confirmed the LD failed to ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for two events in 2021 and 2022.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2021 and 2022 proficiency testing (PT) and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory for one of three testing events in 2021. Findings: 1. Review of WSLH PT results event 2021-B showed: pCO2 60%, ionized Calcium 80% and Lactate 60% with no corrective action plan. 2. Interview with the TC #2 on November 15, 2022 at 12:30 PM confirmed PT event 2021-B had no approved corrective action plan when PT results were unacceptable.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Siemens Rapid Point 500 blood gas analyzer quality control (QC) and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure the QC program is established and maintained to assure the quality of the laboratory services provided. Findings: 1. Review of the Siemens Rapid Point 500 blood gas analyzer QC for the analytes chloride, glucose, ionized calcium, lactate, pCO2, pH, pO2, potassium, sodium, carboxyhemoglobin, hemoglobin, methemoglobin and oxyhemoglobin showed no documentation of QC from January 2021 to September 1, 2022. The laboratory could not provide the number of patients that blood gases were reported during this time frame. 2. Interview with the TC #2 on November 15, 2022 at 12:15 PM confirmed the LD failed to ensure the QC program is established and maintained for the Siemens Rapid Point 500 blood gas analyzer.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Siemens Rapid Point 500 blood gas analyzer quality control (QC) and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure the QC and quality assessment program is established and maintained to identify failures in quality as they occur. Findings: 1. Review of the Siemens Rapid Point 500 blood gas analyzer QC for the analytes chloride, glucose, ionized calcium, lactate, pCO2, pH, pO2, potassium, sodium, carboxyhemoglobin, hemoglobin, methemoglobin and oxyhemoglobin showed no documentation of QC from January 2021 to September 1, 2022. The laboratory could not provide the number of patients that blood gases were reported during this time frame. 2. Interview with the TC #2 on November 15, 2022 at 12:15 PM confirmed the LD failed to ensure the QC and quality assessment program is established and maintained for the Siemens Rapid Point 500 blood gas analyzer.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of performance evaluations and interview with the technical consultant (TC) #2, the technical consultant (TC) failed to evaluate and document annual performance evaluations for one of nine testing personnel (TP) in 2021.

	Findings: 1. Review of performance evaluations showed no annual performance evaluation for TP #5 in 2021. 2. Interview with the TC #2 on November 15, 2022 at 12:00 PM confirmed the technical consultant failed to evaluate and document annual performance evaluation for TP #5 in 2021.