

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0678066	(X3) Date Survey Completed 04/28/2021
Name of Provider or Supplier Crmc Abg Lab	Street Address, City, State 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Siemens Rapid Point 500 and the Siemens EPOC instrumentation performing similar tests on different methodologies, lack of documentation of the comparison studies between instruments performing blood gas analysis and interview with testing personnel # 2 the laboratory failed to meet the condition of analytic systems. (Refer to D5775) This is a repeat deficiency cited during previous survey conducted August 18, 2018.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on review of temperature and humidity logs, policies and procedures and interview with testing personnel (TP) #1, the laboratory failed to define criteria for the accurate and reliable test system operation and test result reporting for blood gas analyzers from Nov 19, 2019 to date April 28, 2021. Findings: 1. The Siemens Rapidpoint 500 blood gas manual specifies the room temperature range must be between 15-30 degrees C and humidity must be between 5-85%. 2. Review of temperature logs showed a lack of documentation for room temperature and humidity from November 19, 2019 to date April 28, 2021. 3. Interview with TP #2 on April 28 at 130 P.M. confirmed the laboratory failed to define criteria for humidity and ambient temperature and monitor and document room temperature and humidity.

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 2019 and 2020 performance specifications for the Siemens Rapid Point 500 blood gas analyzer, the Siemens EPOC blood gas analyzer and interview with testing personnel #2, the laboratory failed to verify the manufacturer's reference intervals (normal values) for 9 out of 9 analytes for the two new test systems prior to patient testing. Findings: 1. Review of verification of method performance of Siemens Rapid Point 500 Blood Gas tests of pCO₂, pH, pO₂, glucose, Ionized Calcium, Sodium, Potassium, Chloride and Lactate revealed the laboratory failed to evaluate and verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to patient testing in November 2019. 2. Review of verification of method performance of Siemens EPOC Blood Gas tests of pCO₂, pH, pO₂, glucose, Sodium, Potassium, Chloride and Lactate revealed the laboratory failed to evaluate and verify the reference intervals (normal values) were appropriate for the laboratory's patient population prior to patient testing in November 2019. 2. Interview with testing personnel #2 on August 28, 2021 at 1:15 PM confirmed the laboratory failed to verify Siemens RapidPoint 500 and Siemens EPOC reference intervals (normal values) were appropriate for their own patient population prior to patient testing in November 2019.

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 review of blood gas instrument records for 2019-2020 and interview with the testing personnel#2, the laboratory failed to evaluate and define the relationship between instruments / methodologies performing the same tests. Findings: 1. Review of blood gas instrument records revealed the laboratory performs blood gases on the Siemens RapidPoint 500 and the Siemens EPOC. The instrument comparison records failed to show how the laboratory defined limits of acceptability and evaluate the variance between instruments/methodologies performing the same tests. 2. Interview with the Testing Personnel #2 on April 28, 2021 at 1:30 PM confirmed, the laboratory failed to establish criteria for acceptable differences between instruments /methodologies performing the same tests.