

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0678066	<b>(X3) Date Survey Completed</b>  05/22/2024
<b>Name of Provider or Supplier</b>  Crmc Abg Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review survey was completed on May 22, 2024, the laboratory was found to be out of compliance with the following condition level deficiencies: 42 C.F.R 493.803 Condition: Successful Participation 42 C.F.R 493.1403 Condition: Moderate Complexity Laboratory Director
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of WSLH proficiency testing (PT) chemistry results for 2024 and 2023 and interview with the technical consultant (TC) #2 on May 16, 2024 at 4:30 PM</p>

	<p>, the laboratory failed to successfully participate in PT. Refer to D-tag 2096, unsatisfactory performance in three out of four consecutive PT events for PO2 (oxygen partial pressure) blood gas.</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of WSLH proficiency testing (PT) chemistry results for 2024 and 2023 and interview with the technical consultant (TC) #2, the laboratory failed to achieve satisfactory performance for PO2 (oxygen partial pressure) blood gas in three out of four consecutive testing events. Findings: 1. Review of the WSLH PT chemistry results for the first event of 2024 showed the laboratory obtained an unsatisfactory score of 0 percent for the analyte PO2 blood gas. 2. Review of the WSLH PT chemistry results for the third event of 2023 showed the laboratory obtained an unsatisfactory score of 60 percent for the analyte PO2 blood gas. 3. Review of the WSLH PT chemistry results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 60 percent for the analyte PO2 blood gas. 4. Interview with the technical consultant (TC) #2 on May 16, 2024 at 4:30 PM confirmed the laboratory failed to achieve satisfactory performance for PO2 blood gas in three out of four consecutive testing events.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of WSLH proficiency testing (PT) chemistry results for 2024 and 2023, and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to provide overall management and direction to the laboratory. (Refer to D6016.)</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of WSLH proficiency testing (PT) chemistry results for 2024 and 2023, and interview with the technical consultant (TC) #2, the laboratory director (LD) failed to ensure successful participation in an HHS approved proficiency testing program. Findings: 1. Review of the WSLH PT chemistry results for the first event of 2024 showed the laboratory obtained an unsatisfactory score of 0 percent for the analyte PO2 blood gas. 2. Review of the WSLH PT chemistry results for the third event of 2023 showed the laboratory obtained an unsatisfactory score of 60 percent for the analyte PO2 blood gas. 3. Review of the WSLH PT chemistry results for the first event of 2023 showed the laboratory obtained an unsatisfactory score of 60 percent for the analyte PO2 blood gas. 4. Interview with the technical consultant (TC) #2 on May 16, 2024 at 4:30 PM confirmed the laboratory director (LD) failed to ensure successful participation in an HHS approved proficiency testing program.