| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>27D0663007 | (X3) Date Survey Completed<br>11/03/2022 |
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| **Name of Provider or Supplier**<br>Central Montana Medical Center | **Street Address, City, State**<br>408 Wendell Ave, Lewistown, MT | |

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 |
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| **D3021** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(c)(1)<br><br>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Immunohematology records, policies, and interview with technical supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood or blood products from January 1, 2021 to November 3, 2022. Findings: 1. Review of Immunohematology records revealed the laboratory failed to take and document the temperatures of blood or blood products upon receipt of new shipments to the laboratory from January 1, 2021 to November 3, 2022. 2. Review of Policy "LAB-BB-002-1; Inventory Management: Order, Receipt, Return and Transfer" lacked temperature requirements for acceptance of blood or blood product and instructions for documentation. 3. Interview with TS #1 on November 3, 2022 at 1:00 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood or blood products from January 1, 2021 to November 3, 2022. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of annual competency files for 2021 and 2022, and interview with the technical supervisor (TS) #1, the laboratory failed to establish and follow a written policy to assess six of eleven employee's competencies for year 2021. Findings: 1. Review of personnel records lacked documentation to prove either semiannually competency during the 1st year of patient testing or annual competency of testing personnel for year 2021 for 6 out of 11 testing personnel (TP#6, TP#7, TP#8, TP#9, TP#10, and TP#11) listed on the CMS Form 209. 2. Review of Blood Gas Analysis and CO-Oximetry policy CPC-DT-ABG.005 lacks description of the six required procedures for competency assessment over time and the required training prior to patient testing. 3. Interview on November 3, 2022 at 10:15 AM with TS #1, confirmed the lack of documentation to prove competency assessments for 6 of 11 testing personnel listed on the CMS Form 209 for year 2021. |
| **D5425** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(3)<br><br>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with the technical supervisor (TS) #1, the laboratory failed to establish one of one Individualized Quality Control Plan (IQCP) for the AVOXimeter 4000 Co-Oximetry to include a risk assessment (RA), quality control plan (QCP) and quality assessment (QA) from January 1, 2021 to November 3, 2022. Findings: 1. Observed in the Respiratory Unit on November 3, 2022 at 10:00 AM, an AVOXimeter 4000 analyzer testing analytes: total hemoglobin (tHb), oxyhemoglobin saturation (%O2Hb), carboxyhemoglobin (%COHb), and methemoglobin (%MetHb). 2.Review of AVOXimeter 4000 Operator's Manual revealed the laboratory failed to follow the manufacturer's instructions to perform and document "Daily optical quality control" and "Weekly testing of one level of liquid controls.". 3. Review of Blood Gas Analysis and CO-Oximetry policy CPC-DT-ABG. 005 lacks description for daily and weekly QC requirements for the AVOXimeter 4000 Co-Oximetry analyzer. 4. No daily QC records of the yellow and orange filters were available for review to ensure the results for THb, %O2Hb, %COHb, and % MetHb were within expected range and the instrument was properly calibrated. 5. No weekly QC records of Multi-4 CO-Oximeter or RNA CO-Oximeter liquid control results for THb, %O2Hb, %COHb, and %MetHb were available for review to verify results are within expected range. 6. No IQCP was available to review that established a RA, QCP or QA for the AVOXimeter 4000 Co-Oximetry to allow for alternative QC frequency. 7. Interview with the TS #1 on November 3, 2022 at 11:15 AM, confirmed these findings. |
| **D5535** | ROUTINE CHEMISTRY<br>CFR(s): 493.1267(a)(d)<br><br>For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of blood gas calibration records, Individualized Quality Control Plan (IQCP), OPTI CCA-TS Operator's Manual, and an interview with Technical Supervisor (TS) #1, the laboratory failed to perform and document quarterly tHb calibration as per their procedures from January 1, 2021, to November 3, 2022. Findings: 1. Review of blood gas IQCP revealed the laboratory failed to perform tHb calibration verification as stated, "calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer." 2. Review of the OPTI CCA-TS Operator's Manual revealed the laboratory failed to perform calibrations as stated: "4.1 Calibration of the tHb channel is required every 3 months." 3. No records of tHb calibrations were available for review. 4. Interview with the (TS) #1 on November 3, 2022, at 11:30 AM, confirmed the laboratory failed to perform tHb calibration every three months on the OPTI CCA-TS Blood Gas Analyzer as per their IQCP from January 1, 2021, to November 3, 2022. |
| **D5537** | ROUTINE CHEMISTRY<br>CFR(s): 493.1267(b)(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, Avoximeter 4000 Operator's Manual and interview with technical supervisor (TS) #1, the laboratory failed to test one sample of quality controls (QC) material within eight hours of patient testing on the AVOXimeter 4000 whole blood CO-Oximeter from January 1, 2021 to November 3, 2022. Findings: 1. A review of patient results report #22-148-2287 for arterial blood gas released on 5/29 /2022 revealed the laboratory failed to perform both a low and high level of QC the day of patient specimen testing on the AVOXimeter 4000 Co-Oximetry. 2. No IQCP was available to review that established a RA, QCP or QA for the AVOXimeter 4000 Co-Oximetry to allow for alternative QC frequency. (See 5425) 3. Review of test volume sheet revealed 56 arterial blood gas tests were performed from October 1, 2021 to November 1, 2022. 4. Interview on November 3, 2022 at 11:00 AM with the TS #1, confirmed the laboratory failed to run a control each 8 hours of patient testing on the AVOXimeter 4000 whole blood oximeter analyzer from January 1, 2021 to November 3, 2022. |