| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D0303802 | 03/29/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Medical Center Barbour | 820 W Washington Street, Eufaula, AL | |

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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| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Seimens epoc System records, and an interview with the Laboratory Manager, the laboratory failed to ensure the optional IQCP (Individualized Quality Control Plan) was valid before performing patient testing from November 2022 through March 2023. The surveyor noted the document failed to included three of three required elements for a valid IQCP. The findings include: 1. A review of records for the Seimens epoc System (used by Respiratory Therapy for Arterial Blood Gas [ABG] testing) revealed the laboratory ran Level 1 and 3 quality controls (QC) on ABG test cards on the two readers (#34489 and #34595) approximately once a month, as follows: A) 11/22/2022: Two levels of QC on both readers B) 12/29/2022: Two levels of QC on both readers C) 1/18/2023: Two levels of QC on both readers D) 1/29 /2023: Two levels of QC on Reader #34595 only E) 2/10/2023: Level 3 on Reader #34489 and Level 1 on Reader #34595 F) 3/14/2023: Two levels of QC on both readers 2. A review of the epoc System Procedure Manual on page 12 of 33, under "QUALITY CONTROL" revealed, "...From each lot in each shipment of cards, analyzed at least two (2) levels of fluid controls in duplicate using any verified reader." 3. During an interview on 3/29/2023 at 3:00 PM, the surveyor explained the laboratory is required to perform two levels of QC each day of patient testing unless |

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| | an IQCP has been implemented, and approved by the Laboratory Director. The Laboratory Manager stated the Respiratory Therapy laboratory had implemented an IQCP, and it was in the back of the procedure manual. 4. As the interview continued on 3/29/2023 at 3:15 PM, the surveyor and Laboratory Manager reviewed the "IQCP" in the procedure manual. The surveyor noted the Laboratory's "IQCP" was actually the manufacturer's example of a "Risk Assessment", and the laboratory had failed to make it specific for their facility. The "IQCP" further failed to include a "QC Plan" (specifying the number, type, frequency of testing, and acceptability criteria of the quality controls), and the laboratory must at least adhere to the manufacturer's instructions in QC performance, which they had failed to do on 1/29/2023 and 2/10 /2023. In addition, the IQCP failed to include a Quality Assurance Plan (to monitor for any performance issues or problems). The surveyor also explained the Laboratory Director must review and document approval (via signature and date) of the IQCP before implementation. 5. On 3/29/2023 at 3:30 PM, the surveyor asked about patient ABG testing on the epoc System. The Laboratory Manager stated patient testing began 11/15/2023, and as of 3/29/2023, 135 patient ABG's were run, with QC only run on the six dates listed above. . |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Seimens epoc System records, and an interview with the Laboratory Manager, the laboratory failed to ensure two levels of quality controls were performed each day of patient testing from November 2022 through March 2023. The findings include: 1. A review of records for the Seimens epoc System (used by Respiratory Therapy for Arterial Blood Gas [ABG] testing) revealed the laboratory ran Level 1 and 3 quality controls (QC) on ABG test cards on the two readers (#34489 and #34595) approximately once a month, as follows: A) 11/22/2022: Two levels of QC on both readers B) 12/29/2022: Two levels of QC on both readers C) 1/18/2023: Two levels of QC on both readers D) 1/29/2023: Two levels of QC on Reader #34595 only E) 2/10/2023: Level 3 on Reader #34489 and Level 1 on Reader #34595 F) 3/14 /2023: Two levels of QC on both readers 2. During an interview on 3/29/2023 at 3:00 PM, the surveyor explained the laboratory is required to perform two levels of QC each day of patient testing unless an IQCP has been implemented, and approved by the Laboratory Director. The Laboratory Manager stated the Respiratory Therapy laboratory had implemented an IQCP, and it was in the back of the procedure manual. However, a review of the document revealed it was not a valid IQCP. [Refer to D5445.] 3. On 3/29/2023 at 3:30 PM, the surveyor asked about patient ABG testing on the epoc System. The Laboratory Manager stated patient testing began 11/15/2023, and as of 3/29/2023, 135 patient ABG's were run, with QC only run on the six dates listed above. SURVEYOR ID# 32558 Licensure and Certification Surveyor |