| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br>01D2176697 | **(X3) Date Survey Completed**<br>02/11/2021 |
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| **Name of Provider or Supplier**<br>Robert Cater Md Pc | **Street Address, City, State**<br>1425 Greenbrier Dear Road, Anniston, 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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| **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 reviews of the Hematology quality control (QC) records and the patient logs, and an interview with the Laboratory Director, the laboratory failed to perform at least two levels of QC each day of patient testing. The surveyor noted three days in 2020 when the laboratory failed to perform QC prior to patient CBC (Complete Blood Count) testing. The findings include: 1. A review of the 2020 monthly cumulative QC records and patient logs for the Medonic Hematology analyzer revealed no documentation of QC on three days of patient CBC's testing, as follows: A) 5/8/2020: 1 patient CBC B) 8/7/2010: 4 patient CBC's C) 9/3/2020: 8 patient CBC's 2. A review of corrective action revealed the physician (who is also listed as the Clinical Consultant on Form CMS 209--Laboratory Personnel Report) documented review of the patient CBC's performed in September 2020, however there was no documentation of review for patient CBC's performed in May and August 2020. 3. During an interview on 2/11/2021 at 1:55 PM, the surveyor reviewed the above findings with the Laboratory Director. The Director had documented review of QC requirements before patient testing with the Testing Personnel (TP), however the TP stated they had not run QC because some days "they were too busy". . |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g) |

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| | (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of the Hematology quality control (QC) records and the patient logs, a review of the Medonic M-Series instructions on how to perform QC, and an interview with the Laboratory Director, the laboratory failed to ensure at least two levels of quality control were acceptable, prior to analyzing patient specimens and reporting the results. The surveyor noted 19 days of patient CBC (Complete Blood Count) testing when QC failures occurred from August thru December 2020. The findings include: 1. A review of the 2020 monthly cumulative QC records and patient logs for the Medonic Hematology analyzer revealed 19 days of patient CBC testing when at least two levels of QC were outside acceptable ranges, as follows: A) August 2020: day (8/14/20); 1 patient CBC B) September 2020: 1 days 9/15-9/30/2020; 66 patient CBC's C) October 2020: 4 days (10/1, 10/5, 10/16 and 10/19/2020); 24 patient CBC's D) December 2020: 2 days (12/1 and 12/18/2020): 5 patient CBC's 2. A review of corrective action revealed the physician (who is also listed as the Clinical Consultant on Form CMS 209--Laboratory Personnel Report) documented review of the patient CBC's performed in September 2020, however there was no documentation of review for patient CBC's performed in the other three months. 3. During an interview on 2/11/2021 at 1:55 PM, the surveyor reviewed the recurring QC failures with the Laboratory Director, and asked if there was a problem with the instrument. The Director stated, no, there were no problems with the Medonic. The Director stated the testing personnel were not running the QC as per manufacturer's instructions (see below); they were impatient, did not allow the QC vials to come to room temperature, and were not inverting and mixing the QC well. 4. A review of the Medonic M-Series "Beginning of Day" instructions, revealed the following: "... Daily Startup Sequence ... 2. Perform a Quality Control Check a. Prepare controls in accordance to the control package insert. Allow controls to reach room temperature for 30 minutes. Manually mix controls by gently rolling between hands and by gentle inversion. ..." . |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of quality control (QC), patient records and, quality assurance (QA) reports, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to ensure the corrective actions implemented for multiple months when QC was not performed or was outside acceptable ranges effectively remediated a systemic problem identified in the analytic system. The findings include: 1. A review of August-December 2020 QC records for the Medonic M-Series Hematology analyzer revealed at least one level of QC was not run or was outside acceptable ranges approximately fifty percent of the time during this period. The surveyor further |

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| | noted 22 days (in a five month period) of patient CBC testing when QC was not performed or two out of three levels were outside acceptable ranges. (Refer to D5447 and D5481.) 2. A review of the QA Reports revealed the Laboratory Director documented monthly reviews of analytic system parameters with her findings and the corrective actions that needed to be taken to correct problems. The surveyor noted recommended corrective actions were not followed to ensure patient testing was not impacted on days when two out of three levels of QC were outside acceptable ranges or not run. The Laboratory Director instructed personnel to "pull patient CBC's for review by the physician" (May, August, October and December 2020), however there was no documentation of the physician's review of the patient results. 3. The surveyor further noted the Director documented monthly counseling and retraining of the testing personnel, however the same QC failures continued to occur. 4. During an interview on 2/11/2021 at 1:55 PM, the surveyor reviewed the recurring QC failures with the Laboratory Director, and asked if there was a problem with the instrument. The Director stated, no, there were no problems with the Medonic. The Director stated the testing personnel were not running the QC as per manufacturer's instructions (refer to D5481); they were impatient and did not allow the QC vials to come to room temperature, and were not inverting and mixing the QC well. The Director also stated on days when QC was not run before patient CBC's, the testing personnel had stated they were too busy to run the QC. (Refer to D5447.) The surveyor then asked the Director if she had discussed these problems with the Practice Manager and the Physician (Clinical Consultant) / Owner of the Practice. The Director answered, "No." 5. During the exit summation with the Laboratory Director, the Physician / Owner, the Practice Manager, and Testing Personnel #1 and #2, the surveyor reviewed the numerous QC problems since the laboratory began patient CBC testing in May 2020; corrective actions had failed to remediate the recurring problems. The surveyor explained the facility was required to re-evaluate procedures in the laboratory and implement a mechanism to ensure Hematology QC was run and at least two levels were within acceptable ranges each day of patient CBC testing. . |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of quality control, patient records, and quality assurance records, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure additional corrective actions were implemented to effectively remediate a systemic problem identified in the analytic system. After multiple months of QC problems, the Director failed to re-evaluate procedures in the laboratory, and implement a mechanism to ensure patient testing was not performed until Hematology QC was run and at least two levels were within acceptable ranges. The findings include: Refer to D5793. SURVEYOR ID #32558 Licensure and Certification Surveyor |