| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 01D0304240 | 10/09/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| J Michael Karst Md Pa | 4485 Atlanta Highway, Montgomery, 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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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of MLE (Medical Laboratory Evaluation) proficiency testing (PT) records (attestation statements), a review of personnel training records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure proficiency testing was performed by personnel who routinely performed laboratory testing on patient specimens. This affected one of six PT events reviewed by the surveyor. The findings include: 1. A review of the PT records for 2018 MLE - M1 testing event, performed in the first quarter of 2018, revealed the Technical Consultant signed the attestation statement as the testing personnel for the Hematology testing (Complete Blood Count). 2. Based on a review of the personnel training records, Testing Personnel (TP) #1 had trained on 11/30/2017 - 12/28/2017 to perform the laboratory testing, including Complete Blood Count testing. 3. In an interview on 10/09/2018 at 11:35 AM, the surveyor asked the Technical Consultant (TC) if he had performed the testing for Event 1 of 2018, and why. The Technical Consultant stated he had new personnel, and wanted to ensure the proficiency testing was done correctly. The TC stated TP#1 was trained, but still not experienced. The TC further explained he was not a usual laboratory testing personnel of patient specimens, and stated he had never performed testing on a patient specimen in this laboratory. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii) |

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| | 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of MLE (Medical Laboratory Evaluation) proficiency testing (PT) records and an interview with the Technical Consultant (TC), the surveyor determined the Laboratory Director failed to ensure results for PT Event 2017 MLE - M1 was reviewed and evaluated by the technical staff to assure problems were identified and corrective actions were implemented to prevent reoccurrence. This affected one of six PT events reviewed by the surveyor. The findings include: 1. A review of the MLE PT records for 2017 revealed the laboratory scored zero percent (0 %) for the vaginal wet preparation for the first event (2017 MLE -M1). This provider performed microscopy testing was performed by the Laboratory Director. 2. The Laboratory Director nor Technical Consultant implemented and documented corrective actions for this failed performance of proficiency testing. 3. In an interview on 10/09/2018 at 11:19 AM, the TC reviewed the PT records and stated the physician (Laboratory Director) had performed the testing. The TC acknowledged the failing score of the vaginal wet preparation. The TC further stated he only reviewed the CBC (Complete Blood Count)/Hematology testing, and would ask the physician what he did as corrective action. |
| **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 a review of Hematology quality control (QC) records, a review of patient data logs and instrument printouts, a review of the laboratory's "Coulter AcT Diff Procedure" from the laboratory manual, and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to ensure a quality assessment program was maintained to assure appropriate quality controls limits were established, acceptable ranges were programmed in the instrument and observed by the technician, on each day of patient testing. The Laboratory Director failed to ensure laboratory testing staff repeated quality control, when flagged by the instrument as out-of-limits, according to policy and procedure and to ensure accuracy of CBC (Complete Blood Count) testing. This affected multiple days in 2018, based on the surveyor's review. The findings include: 1. A review of the Hematology QC records revealed numerous days when the quality control values were flagged out-of-limits, according to the limits indicated on the daily QC printouts from the instrument. 2. The instrument printouts revealed the following: On 1/31/2018, the MCV and RDW |

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| | flagged out-of-range on the low control; the RBC (Red Blood Cell Count) and RDW flagged out on the normal level of QC; and the WBC (White Blood Cell Count) and MCV flagged out-of-range on the high level of QC. There was no documentation any of these controls were repeated for accuracy and acceptability. At this time of the review, the Technical Consultant (TC) stated the staff were trained to review each analyte of each level of control, and as long as two of the three of each analyte was within range, the staff accepted the QC. The TC also stated the staff should repeat the testing of all out-of-range quality control for all measured analytes, and RBC and MCV should have been repeated on this day. 3. On 2/01/2018, multiple analytes were flagged as out-of-limits, including the WBC on the normal and high levels of quality control. There was no documentation of repeat testing of QC, which flagged as out-of-limits. A review of patient data logs and instrument printouts revealed 7 patients specimens were tested. On 3/07/2018, the platelet counts were flagged as out-of-limits on the normal and high levels of QC with no repeat testing documented. A review of patient data logs and instrument printouts revealed 4 patients specimens were tested. On 9/04/2018, the Hematocrit was flagged as out-of-limits on two of the three levels of QC. There was no documentation of repeat testing of the QC. The patient data logs and instrument printouts revealed 7 patient specimens were tested. Again on 9/07, 9 /10, and 9/11 of 2018, at least one measured analyte flagged as out-of-limits on two levels of QC, with no documentation of repeat testing of quality control. Patient specimens were tested on these days. 4. The laboratory's "Coulter AcT Diff Procedure" included the following instructions and guidelines: "...6. ...a. There are three levels of 4-C control, Low, High and Normal. ...d. Each control assay has an expected range. When new lots of controls are received, they are to be tested in parallel with the current lot to establish the mean value for each level of control. i. Run each control daily for a minimum of 5 days to establish a new mean based on the calibration of the instrument. ii. Sum the values for each directly measured parameter for each control level and divide by the total number of data points collected for each parameter to determine the mean value for the new control levels. iii. This new mean should be within the expected limits of the control assay sheet but not necessarily the mean value assigned on the assay sheet. iv. This new mean will be the new assay value that is used when we enter the control values once the old lot number has been completed. e. These controls are to be run daily to ensure the accuracy of the instrument's performance f. Two levels of control will be run each morning on startup prior to patient analysis. g. The remaining level will be performed in the early afternoon to ensure continued accuracy of the instrument's performance. h. Controls must be within the stated control limits prior to patient analysis i. All out of control incidents must be evaluated and resolved prior to patient analysis. Entering Cell Control Information: Each time a new lot of control material has been validated, the new mean values must be input into the control program of the instrument..." 5. On 10 /09/18 at 11:19 AM, the surveyor asked the Technical Consultant to explain the QC policy, procedure and practices of the laboratory, particularly how staff determine acceptable quality control. The TC stated the testing staff did not understand lot-to-lot QC verification (establishing ranges), and QC limits were not always changed in the instrument to reflect the current acceptable ranges. The TC stated he instructed staff to keep the manufacturer's assay sheets next to the instrument for QC acceptability determination. However, the ranges (limits) were subject to lot-to-lot verifications and any adjustments to the calibrations (there were many). The TC further stated lot-to-lot verifications were not being done nor was repeat testing of flagged quality control, as per the laboratory's policy and procedure. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9) |

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| | The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of personnel credentials and training records, a lack of documentation, and an interview with the Technical Consultant, the surveyor determined the Technical Consultant failed to evaluate the competency of Testing Personnel (TP) #1 at least semi-annually during the first year of employment as testing personnel of moderate complexity testing. This affected one of two testing personnel. The findings include: 1. A review of the personnel records revealed initial training for TP #1 of CBC (Complete Blood Count) testing on the Beckman Coulter Act Diff occurred on 11/30/2017 through 12/28/2017. 2. The personnel records did not include a semi-annual competency evaluation for TP #1. 3. At 9:30 AM on 10/09 /18, the surveyor asked the Technical Consultant if he had assessed the competency of TP #1, since the date of hire and initial laboratory training. The Technical Consultant reviewed the manual's records and confirmed he had not performed a semi-annual competency evaluation for TP #1. Patricia Watson, BS MT (ASCP) Licensure and Certification Supervisor |