

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2041950	<b>(X3) Date Survey Completed</b>  06/05/2024
<b>Name of Provider or Supplier</b>  Pell City Internal And Family Medicine	<b>Street Address, City, State</b>  41 Eminence Way Suite A, Pell City, AL	
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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology calibration records, a review of the Medonic user manual, and an interview with the TC (Technical Consultant), the Laboratory failed to perform calibrations on the Medonic Hematology analyzer every six months as per the manufacturer's requirements. This was noted for three of three calibrations in 2023 and 2024. The findings include: 1. The Hematology calibration records revealed the Medonic was calibrated on 8/2/2022. There was no evidence of calibrations performed for February 2023, August 2023, and February 2024. 2. A further review of the Medonic user manual, pg. 60, revealed, "It is recommended to calibrate the instrument every 6 months." 3. During an interview on 6/5/2024, at 1:15 PM, the TC confirmed the calibrations for 2023 and first half of 2024 were not performed due to the Testing Personnel being out on leave.</p>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of the C-V (Calibration Verification) records and an interview with the TC (Technical Consultant), the laboratory failed to ensure C-V was performed and documented on the BC (Beckman Coulter) AU 480 Chemistry analyzer. This was noted for two out of four C-V opportunities in 2023 and 2024. The findings include:

1. A review of the records for the BC AU 480 Chemistry analyzer revealed the following analytes were calibrated with two on-board calibrators: 1. DBil (Direct Bilirubin), TBil (Total Bilirubin), Na (Sodium), K (Potassium), Cl (Chloride), CO<sub>2</sub> (Carbon Dioxide), BUN (Blood Urea Nitrogen), Creat (Creatinine), Glu (Glucose), ALT (Alanine Transaminase), AST (Aspartate Transferase), ALP (Alkaline Phosphatase), Ca (Calcium), ALB (Albumin), TP (Total Protein), HDL (High Density Lipoprotein), Chol (Cholesterol), and Trig (Triglycerides).
2. Analytes calibrated with less than three calibrators must have a semi-annual C-V, as per CLIA regulatory requirements.
3. A review of the BC AU 480 records revealed documentation of C-V performed on 10/3/2022 and 4/5/2023 only. There was no evidence of C-V's performed for the second half of 2023 and the first half of 2024.
4. During an interview on 6/5/2024, at 1:15 PM, the TC confirmed the C-V's for the second half of October 2023 and the first half of 2024 were not performed due to the Testing Personnel being out on leave.