

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2160358	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Fort Payne Care Plus Llc	Street Address, City, State 3000 Gault Ave, Fort Payne, 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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION 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 M-series User's Manual, and an interview with Testing Personnel #2, the laboratory failed to follow the manufacturer's instructions to perform quality controls after calibration, and before running patient samples. This was noted on one of four 2019 - 2021 calibrations reviewed. The findings include: 1. A review of Hematology records revealed the Medonic was calibrated on 07/09/2020 at 2:21 PM. However, quality control was not performed following the calibration and two patient samples were tested on 07/09/2020 at 2:32 PM and 2:35 PM. 2. A review of the Medonic M-series User's Manual revealed in Section 7 Calibration(Page 62) "...18. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. See section 1.6 to perform QC." 3. During an interview on 11/16/2021 at 2: 15 PM, Testing Personnel #2 confirmed the above findings.</p>