

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2176697	(X3) Date Survey Completed 12/21/2022
Name of Provider or Supplier Robert Cater Md Pc	Street Address, City, State 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
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 records, the manufacturer's user manual, and an interview with the Laboratory Director, the Laboratory failed to perform calibrations on the Medonic M series Hematology analyzer every six months as per the manufacturer's instructions. The laboratory failed to perform two of five calibrations due in 2021 and 2022. The findings include: 1. A review of the Hematology calibration records revealed the Medonic M series was calibrated 10/28/2021 and then ten months later on 8/18/2022. There was no documentation of a calibration the first half of 2021 and 2022. 2. A further review of the Medonic user manual revealed on page 60, "It is recommended to calibrate the instrument every 6 months." 3. During an interview on December 21, 2022, at 10:41 AM, the Laboratory Director confirmed the calibrations due in April 2021 and April 2022 were not performed.</p>