

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305406	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Family Medical Semmes	Street Address, City, State 7505 Moffat Rd, Mobile, 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 reviews of the Hematology calibration records, the Medonic M Series Operator's Manual, and an interview with Testing Personnel #1, the laboratory failed to follow the manufacturer's instructions to perform quality control after calibration, and before running patient samples. This was noted on one of five calibrations reviewed for 2020 - 2022. The findings include: 1. A review of Hematology records revealed the Medonic M Series instrument was calibrated on 03/02/2021 at 3:46 PM, however, quality control was not performed until 03/03/2021. A review of the 03/02 /2021 "All Sample Log" revealed two patient CBC's (Complete Blood Counts) were run after the calibration at 4:59 PM and 5:29 PM. 2. A review of the Medonic M Series Operator's Manual revealed under section 7.2 Calibration, " ...17. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ...". 3. During an interview on 5/17/2022 at 1:00 PM, Testing Personnel #1 verified controls should be run after every calibration. Testing Personnel</p>

confirmed two patient CBCs were performed after the calibration on 03/02/2021, and stated "It was the end of the day, and I just forgot." SURVEYOR ID# 32558
Licensure and Certification Surveyor