

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2107019	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Ourmed Llc	Street Address, City, State 9188 Eastchase Parkway, 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
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 reviews of the Beckman Coulter AcT diff analyzer Operator's Guide, the calibration and quality control records, and an interview with the Director of Operations (also Testing Personnel #1 on the Form CMS-209), the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for one of two calibrations of the Hematology analyzer performed in 2018. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff revealed the analyzer was calibrated on 7/5/2018 at 9:41 AM. 2. A review of the QC records revealed controls were run in the early morning at approximately 8:24 AM on the above date; there was no documentation QC was performed after the calibrations. 3. A review of the Coulter AcT diff Analyzer Operator's Guide, under the CALIBRATION section revealed, "... 17. Verify calibration by running 4C PLUS Cell Control. ..." 4. During an interview on 1/22/2020 at approximately 1:00 PM with the Director of Operations, the manufacturer's direction to perform QC after calibration of the Hematology analyzer was reviewed in the operator's manual. The Director of Operations confirmed the</p>

testing personnel had missed performing QC after the calibration. When asked if any patient testing was performed after the calibration, the Director stated five patient Complete Blood Counts (CBCs) were performed on 7/5/2020. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor