

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2076406	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Stopwatch Urgent Care	Street Address, City, State 151 N 20th Street, Opelika, 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 Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual, calibration and quality assurance records, and an interview with Testing Personnel (TP) #6, the surveyor determined the laboratory failed to follow the manufacturer's instructions in the performance frequency of calibrations in 2016 - 2017. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer Operator's Manual on page 6-3 revealed the following instructions, "When to Calibrate...At least every six months...". 2. A review of the Hematology records revealed the following: A) 9/29/2016: Documentation of an acceptable calibration B) 7 /24/2017: Documentation of a calibration performed ten months after the previous calibration 3. A review of quality assurance records revealed a note from the Technical Consultant on a 6/30/2016 Calibration Report, asking "Where is 12-16 cal [calibration]?" The Technical Consultant had also made a note directing the testing personnel to check with Abbott Service for documentation of a calibration. 4. During the exit summation interview and review of the records on 6/7/2018 at approximately 3:00 PM, TP #6 was asked if the laboratory had documentation of any Hematology</p>

calibrations performed between 9/29/2016 and 7/24/2017 (ten months later). TP #6 confirmed she had been unable to find any other calibrations for that period. When asked how often the Emerald Hematology analyzer should be calibrated, TP #6 stated, "Every six months". Thus, the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor