

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0884020	<b>(X3) Date Survey Completed</b>  02/25/2020
<b>Name of Provider or Supplier</b>  Doctors Med Care P C	<b>Street Address, City, State</b>  604 Smith Road, Albertville, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 calibration records, the Operator's Manual (on line), and an interview with Testing Personnel (TP) #2, the surveyor determined the laboratory failed to follow the laboratory policy and the manufacturer's instructions in the performance frequency and documentation for one of two calibrations in 2018. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer records revealed the following: A) 8/22 /2017: Documentation of an acceptable calibration reviewed during the previous survey B) 1/12/2018: The manufacturer's assay sheet for Cell Dyn 18 Calibrator Lot # 7252C (Expiry: 1/31/2018) with a note: "Calibrator done 1/12/18. I have no results, they cannot be reproduced. [Name of TP #2]" C) 8/21/2018: Documentation of an acceptable calibration 2. During an interview and review of the records on 2/25/2020 at 1:15 PM, TP #2 confirmed this was her note, and she had no documentation for any Hematology calibration performed in early 2018; TP #2 stated the printouts may have been discarded during cleaning. When asked how often the Emerald Hematology analyzer should be calibrated, TP #2 stated, "the policy required it every six months".</p>

3. A further review of the electronic (available on line) 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...". Thus, the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor