

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304411	<b>(X3) Date Survey Completed</b>  03/20/2019
<b>Name of Provider or Supplier</b>  Keith S Hughes Md Pc	<b>Street Address, City, State</b>  6994 Winton Blount Blvd, Montgomery, 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 Operator's Manual, calibration records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the manufacturer's instructions in the performance frequency of calibrations in 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) 5/10 /2017: Documentation of a valid calibration B) 2/21/2018: Documentation of a calibration performed approximately nine months after the previous calibration 3. During an interview and review of the records on 3/20/2019 at 1:20 PM, TP #1 was asked about calibration frequency, and whether the laboratory had performed a calibration the second half of 2017. TP #1 confirmed the testing personnel were taught calibrations were required every six months, however the staff had missed performing the calibration due in late 2017. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>