

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0700080	(X3) Date Survey Completed 01/30/2019
Name of Provider or Supplier Brookwood Women's Health Pc	Street Address, City, State 2006 Brookwood Med Center Dr Suite 202, Birmingham, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2017 - 2018 Accutest Proficiency Testing records and an interview with Testing Personnel #1, the laboratory failed to document corrective action for two of six surveys with results less than 100 % (percent). The findings include: 1. A review of the Accutest Proficiency Testing survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100% as follows: A) 2017 C3 Hematology: Hematocrit with a score of 80% B) 2018 C3 Hematology: Hemoglobin with a score of 80% 2. In an interview on 1/30 /2019 at 10:30 AM, Testing Personnel #1 was asked if the laboratory had performed corrective action for the analytes with scores less than 100%. Testing Personnel #1 stated this was not done because she had thought corrective action was only required when the laboratory had a failing score. Thus the above noted findings were confirmed. .</p>
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)</p>

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.

This STANDARD is not met as evidenced by:

Based on reviews of the Beckman Coulter AcT diff 2 analyzer Operator's Guide, the calibration and quality control records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to follow the manufacturer's instructions to verify calibrations by running quality controls (QC), for five out of five calibrations of the Hematology analyzer performed in 2017 - 2019. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff 2 revealed the instrument was calibrated on the following dates: A.) 02/03/2017 at 1:36 PM B.) 07/31/2017 at 6:18 PM C.) 12/29/2017 at 2:04 PM D.) 06/26/2018 at 6:14 PM, and E.) 01/09/2019 at 12:23 PM 2. A review of the QC records revealed controls were run in the early morning only on the above dates; there was no documentation QC was performed after the calibrations. 3. A review of the Coulter AcT diff 2 Analyzer Operator's Guide, under the CALIBRATION section on page 5-18 revealed, "...17. Verify calibration by running 4C PLUS Cell Control. ..." 4. During an interview on 1/30/2019 at approximately 11:05 AM with TP #1, the manufacturer's direction to perform QC after calibration of the Hematology analyzer was reviewed in the operator's manual. TP #1 stated she had not previously known of this requirement, thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor