

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2119872	(X3) Date Survey Completed 09/07/2021
Name of Provider or Supplier Your Doctor's Office	Street Address, City, State 8630 Vaughn Road, 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 2 calibration and quality control records, the on-line Operator's Guide, and an interview with the Laboratory Supervisor, 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 performed in 2019. The findings include: 1. A review of calibration records for the Beckman Coulter AcT diff revealed the instrument was calibrated on 5/12/2019 at 2:16 PM. However, there was no documentation QC was run after the calibration. (Three levels of QC were only run in the morning 8:04 to 8:08 AM.) 2. A review of the Coulter AcT diff 2 Operator's Guide (available on-line), under the CALIBRATION section on page 5-16 revealed, "...16. Verify calibration by running 4C PLUS Cell Control. ...". 3. During an interview and review of the records on 9/7/2021 at 4:09 PM, the General Supervisor confirmed the laboratory failed to perform QC after the 5/12/2019 calibration, and further confirmed QC should be performed</p>

after calibrations. The surveyor then asked if any patient CBC's (Complete Blood Counts) were performed after 2:16 PM on 5/12/2019; the Supervisor stated two patient CBC's were run at 3:57 PM and at 5:25 PM. .

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of Hematology quality control (QC) records, and an interview during the exit summation, the laboratory failed to implement additional corrective actions to ensure patient CBC's (Complete Blood Counts) were performed only on days when at least two levels of QC were within acceptable ranges. The surveyor noted four days of patient testing when QC was unacceptable during the review period of 2018 - 2021. The findings include: 1. A review of Hematology and patient records revealed two levels of QC were outside acceptable ranges with patient testing performed as follows: A) 8/25/2018: Seven patient CBC's were run and reported. B) 4/5/2019: Twelve patient CBC's were run and reported. C) 11/8/2020: Seven patient CBC's were run and reported. D) 1/8/2021: Four patient CBC's were run and reported. 2. The documented corrective action for the above incidents was to have the physician review the patient CBCs, and to counsel the testing personnel who worked that date. The surveyor noted the laboratory had no mechanism to track problems on a long term basis; thus the laboratory failed to note this was a systemic recurring incident, and failed to implement further corrective actions to prevent recurrence. 3. During the exit summation on 9/7/2021 at 4:35-4:45 PM, the above noted concerns were reviewed and confirmed with the Technical Consultant and the General Supervisor. .

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on a review of Beckman Coulter AcT diff 2 calibration and quality control (QC) records, a lack of training records for new testing personnel, and interviews with the Technical Consultant and the General Supervisor, the surveyor determined the Technical Consultant failed to ensure: i) initial training for Testing Personnel was performed and documented; ii) training included the requirements for QC to be performed and acceptable each day of patient testing and after instrument calibrations. The findings include: 1. Refer to D5437, D5793, and D6066. .

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel files, and an interview with the Laboratory Supervisor, the surveyor determined the laboratory failed to document the training of eight of eight new Testing Personnel before the testing and reporting of CBC's (Complete Blood Counts) on patient samples. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed eight new Testing Personnel (#1, #2, #3, #4, #5, #6, #7, and # 9) were hired since the previous survey on 8/21 /2018. A review of personnel files revealed no documentation of training to perform CBC's (a moderate-complexity test) on the Beckman Coulter AcT diff 2 for these employees. All had been employed for six months or more, and had performed patient CBC testing. 2. During an interview on 9/7/2021 at 10:15 AM, the surveyor asked the Laboratory Supervisor how new testing personnel were trained; the Supervisor explained, she "walked new testing personnel thru the process of performing a CBC, and observed them for several days". The surveyor explained training should also include maintenance, quality control requirements, calibration, problem resolution, and following the manufacturer's instructions for operation. The surveyor then asked if the training was documented; the Supervisor confirmed it was not. SURVEYOR ID# 32558 Licensure and Certification Surveyor