

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1071931	<b>(X3) Date Survey Completed</b>  02/05/2020
<b>Name of Provider or Supplier</b>  Auburn Pediatric And Adult Medicine	<b>Street Address, City, State</b>  2353 Bent Creek Road Suite 110, Auburn, 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 a review of the Abbott Cell Dyn Emerald Hematology analyzer calibration records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to verify the accuracy of the 2/13/2018 calibration by performing quality controls (QC) before resuming patient testing. This affected one of three calibrations performed in 2018. The findings include: 1. A review of the Abbott Cell Dyn Emerald Hematology analyzer records from the 2/13/2018 calibration performed at 1:21 PM, revealed the testing personnel failed to verify the accuracy of the calibration by running QC afterwards. 2. A further review of the Hematology records revealed QC was only run in the early morning. 3. During an interview and review of the records on 2/5/2020 at 11:38 AM, the Technical Consultant confirmed testing personnel should run QC after a calibration, and ensure the results are acceptable before running patient samples. The surveyor then asked if any patient CBC's (Complete Blood Counts) were performed after 1:21 PM on 2/13/2018; the Technical</p>

Consultant checked the records, and stated two CBC's were performed on patients after the calibration on the above date. Thus, the above noted findings were confirmed. .

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a review of patient results reports and an interview with the Technical Consultant and the Testing Personnel, the laboratory failed to ensure the name and address of the laboratory performing the testing was included on the reports. The findings include: 1. On 2/5/2019 at 2:05 PM, the Technical Consultant and the Testing Personnel were asked about the post-analytical process in the facility. Upon the surveyor's request, the Technical Consultant provided a final report of a patient's results. 2. A review of the Film Array Respiratory Panel 2 Report revealed no name and address of the laboratory performing the tests on the report. These tests had been performed on-site since the previous survey. 3. As the interview continued on 2/5/2019 at 2:15 PM, the surveyor reviewed the report with the Technical Consultant and Testing Personnel (TP) #5, who stated the Biofire Technician set up the testing platform and report; TP #5 further stated the laboratory was unable to modify the report. The surveyor explained the name and address of the laboratory performing the testing were required parameters on the report, and the laboratory must implement a mechanism to ensure this information was included. SURVEYOR ID #32558  
Licensure and Certification Surveyor