

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0995631	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Auburn Urgent Care	Street Address, City, State 1650 A South College, Auburn, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Accutest proficiency testing (PT) records, personnel files, and an interview with the Technical Consultant (TC), the laboratory failed to rotate proficiency testing among all testing personnel who routinely perform moderate complexity patient testing. This was noted on five of six 2016-2017 surveys reviewed. The findings include: 1. A review of the attestation statements revealed Testing Personnel #4 (TP #4) performed 2016- Events #1 and #3, and 2017-Events #1, #2 and #3. 2. A review of the personnel files revealed TP #1 and TP #3 were full time, and had been previously qualified to perform moderate complexity testing since the last survey conducted on 12/9/2015. 3. During an interview conducted on 2/27/2018 at 11:00 AM, the TC confirmed TP #4 had performed five out of six of the PT surveys received in 2016-2017. The TC further stated proficiency testing should be rotated among testing personnel who routinely perform moderate complexity testing on patients.</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)</p>

(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.

This STANDARD is not met as evidenced by:

Based on a review the Beckman Coulter AcT Diff Hematology analyzer calibration records, the laboratory's policy and procedure manual, and an interview with the Technical Consultant (TC), the laboratory failed to perform one of two 2016 calibrations at least every six months per the laboratory's policy. The findings include: 1. A review of the AcT Diff calibration records revealed a calibration was performed on 1/31/2016. The next calibration was not performed until 1/29/2017, one year after the previous calibration. 2. The policy and procedure manual states "Coulter Hematology instrument must be calibrated every 6 months or earlier if needed." 3. During an interview conducted on 2/27/2018 at 1:45 PM, the TC reviewed the calibration records and confirmed the above noted findings.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Quality Control (QC) records for the AcT Diff Hematology analyzer, the patient data log, and an interview with the Technical Consultant (TC), the laboratory failed to ensure at least two levels of QC were within acceptable range before testing patients. This affected one of twelve months reviewed in 2017. The findings include: 1. A review of the QC records for the AcT Diff Hematology analyzer revealed only one level of control was acceptable on 7/23/2017. 2. A review of the patient data log revealed 10 patient Complete Blood Counts (CBC'S) were performed on 7/23/2017. 3. During an interview conducted on 2/27/2018 at 1:45 PM, the TC confirmed at least two levels of QC should be in range before patient testing. The TC also stated patient samples may have been sent out due to the QC outages, however the TC was unable to confirm this. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor