

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0301189	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Urology Centers Of Alabama, Pc	Street Address, City, State 3485 Independence Drive, 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
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Medical Laboratory Evaluation (MLE) proficiency testing records and an interview with Testing Personnel # 1, the surveyor determined the Laboratory failed to ensure Hematology results for one of three 2016 surveys was submitted within the timeframes specified by the proficiency testing program. This affected one of six proficiency testing surveys reviewed. The findings include: 1. A review of the results from the 2016-Event #2 Hematology survey revealed a score of 0 % (percent) due to failure to participate. 2. In an interview conducted on 2/21/2018 at 3:30 PM, Testing Personnel #1 stated the laboratory performed the proficiency testing, but failed to submit the results within the time frame specified by the proficiency testing provider. TP #1 also stated the Microbiology Instrument was out of service and the laboratory did not want to submit a portion of the testing to the proficiency testing provider.</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,</p>

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 of the Cell Dyn Emerald Hematology calibration records and an interview with Testing Personnel #1 (TP #1), the laboratory failed to perform a calibration at least every six months as required by the laboratory's policy. This affected one of three calibrations performed. The findings include: 1. A review of the Cell Dyn Emerald calibration records revealed a calibration was performed on 2/17/16 and 4/27/16. The next calibration was not performed until 9/18/2017, greater than a year after the previous calibration date. 2. In an interview conducted on 2/21/2018 at 3:30 PM, TP # 1 reviewed the calibration records with the surveyor and confirmed the laboratory had no other calibration records for 2017.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on a review of Medical Laboratory Evaluation (MLE) proficiency testing records and an interview with Testing Personnel # 1, the surveyor determined the Laboratory Director failed to ensure Hematology results for one of three 2016 surveys were submitted within the timeframes specified by the proficiency testing program. The findings include: 1. Refer to D2127. Jeremy Westry, BS, MT (ASCP) Licensure and Certification Surveyor