

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0261975	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier University Cancer & Blood Center, Llc	Street Address, City, State 3320 Old Jefferson Road, Building 700, Athens, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Validation survey was completed on May 16, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on 2018 American Proficiency Institute(API) proficiency testing (PT) documents review and an interview with the Technical Consultant (TC), the laboratory failed to maintain satisfactory performance in two (2) consecutive events (2018 2nd event and 2018 3rd event for the specialty of Flow Cytometry. The findings include: 1. A review of 2018 (PT) reports disclosed the laboratory had a 50% CD4 score (2nd Event 2018) and a 50% CD4 score (3rd Event 2018). 2. An interview with the Technical Consultant (TC) in the conference room at approximately 12:39 pm on 05/16/2018 confirmed the laboratory failed API (PT) two out of three events resulting in the unsuccessful performance in Flow Cytometry in 2018.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the</p>

performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on the review of laboratory records and interview with the Technical Consultant (TC), the laboratory failed to establish its own reference range for Amylase and Lipase in the specialty of Chemistry. Findings include: 1.) Quality Control (QC) and performance verification records review revealed the manufacturer's ranges for Amylase and Lipase were still being used. The laboratory failed to establish upper and lower limits for its own testing population. 2.) An interview with the (TC) at approximately 12:15 on 05/16/2019 in the conference room confirmed the laboratory did not establish its own reference ranges for Amylase and Lipase in the specialty of Chemistry.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

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.

This STANDARD is not met as evidenced by:

Based on calibration records review and an interview with the Technical Consultant (TC), the laboratory failed to perform calibrations on the AU480 Chemistry analyzer at least once every 6 months in 2018. Findings include: 1. A review of Chemistry calibration records revealed instrument calibrations were performed only once in 2018. 2. Calibrations were performed; 4/24/2017, 10/6/2017 and 9/26/2018, resulting in an eleven (11) month gap. 3. An interview with the (TC) at approximately 12:25 PM on 05/16/2019 in the conference room confirmed calibrations were not performed at least every 6 months in 2018.